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RESEARCH REPORT NO. 1054397

Final Clinical Study Report – Protocol Q4881g – A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study To Evaluate The Efficacy and Safety of Xolair® (Omalizumab) in Patients With Chronic Idiopathic Urticaria (CIU) Who Remain Symptomatic Despite Antihistamine Treatment (H1) – Report 1054397 – June 2013

Study Sponsor(s)	Genentech Inc.
Study Dates:	First patient randomized: 16 February 2011 Last patient last visit: 17 October 2012
Trial Phase:	Phase III
Indication:	Chronic Idiopathic Urticaria

[redacted]

Affiliation:

[redacted]

Sponsor's Signatory: [redacted], Ph.D.

Personnel Responsible for Clinical and Statistical Analyses:

Study Statistician, [redacted], M.S.
Clinical Scientists, [redacted], M.D. and [redacted], M.D., Ph.D.

GCP Compliance: **This study was conducted in accordance with the principles of GCP**

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SYNOPSIS OF RESEARCH REPORT 1054397 (PROTOCOL Q4881g)

COMPANY: NAME OF FINISHED PRODUCT: NAME OF ACTIVE SUBSTANCE(S):	(FOR NATIONAL AUTHORITY USE ONLY)

TITLE OF THE STUDY / REPORT No. / DATE OF REPORT	Final Clinical Study Report – Protocol Q4881g – A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study To Evaluate The Efficacy and Safety of Xolair® (Omalizumab) in Patients With Chronic Idiopathic Urticaria (CIU) Who Remain Symptomatic Despite Antihistamine Treatment (H1) – Report 1054397 – June 2013
INVESTIGATORS / CENTERS AND COUNTRIES	Principal Investigator: [redacted] 53 centers in 8 countries: United States (35 centers), Germany (5), Poland (4), France (3), Spain (2), Denmark (2), Italy (1), and Turkey (1).
PUBLICATION (REFERENCE)	None
PERIOD OF TRIAL	First patient randomized: 16 February 2011 Last patient last visit: 17 October 2012
CLINICAL PHASE	Phase III
OBJECTIVES	Primary: • To evaluate the efficacy of omalizumab compared with placebo in patients with refractory CIU receiving concomitant H1 antihistamine therapy Secondary: • To evaluate the safety of omalizumab therapy in patients with refractory CIU • To evaluate onset of clinical effect of omalizumab therapy in CIU • To evaluate the dose of omalizumab therapy in patients with refractory CIU • To evaluate duration of response after withdrawal of omalizumab in patients with refractory CIU • To evaluate the quality-of-life benefit of omalizumab therapy in patients with refractory CIU

STUDY DESIGN	A global, Phase III, multicenter, randomized, double blind, placebo controlled, parallel group study
NUMBER OF SUBJECTS	Approximately 300 patients were planned for enrollment; 483 patients were screened and 319 patients were enrolled: 80 patients (placebo), 78 patients (omalizumab 75 mg), 80 patients (150 mg), and 81 patients (300 mg). Among the 319 patients who were randomized, 265 patients (83.1%) completed the study treatment, and 262 patients (82.1%) completed the study. One patient did not receive study drug and was therefore not included in the modified intent to treat (mITT) population (n = 318).
DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION	Patients aged 12–75 years who received the diagnosis of refractory CIU and remained symptomatic despite standard-dosed H1 antihistamine treatment.
TRIAL DRUG / STROKE (BATCH) No.	rhuMAb E25 150 mg 1x Omalizumab: Material Code [redacted], Lot Numbers [redacted] and [redacted]
DOSE / ROUTE / REGIMEN / DURATION	Omalizumab (75 mg, 150 mg or 300 mg) administered subcutaneously every 4 weeks for 24 weeks
REFERENCE DRUG / STROKE (BATCH) No.	rhuMAb E25 PL150 mg 1x Placebo: Material Code [redacted] Lot Numbers [redacted] and [redacted]
DOSE / ROUTE / REGIMEN / DURATION	Placebo administered subcutaneously every 4 weeks for 24 weeks
CRITERIA FOR EVALUATION	
EFFICACY:	The mITT population was the primary analysis population used for baseline characteristics summaries and efficacy analyses. Primary Endpoint: • Change from baseline in the weekly itch severity score at Week 12 Secondary Endpoints: • Change from baseline in urticaria activity score over seven days (UAS7) at Week 12 • Change from baseline in weekly number of hives score at Week 12 • Time to minimally important difference (MID) response in weekly itch severity score by Week 12 • Proportion of patients with UAS7 ≤ 6 at Week 12

	• Proportion of weekly itch severity score MID responders at Week 12 • Change from baseline in weekly size of largest hive score at Week 12 • Change from baseline in Dermatology Life Quality Index (DLQI) at Week 12 • Proportion of angioedema-free days from Week 4 to Week 12 of therapy • Proportion of Complete Responders (UAS7 = 0) at Week 12
PHARMACOKINETICS (PK) AND PHARMACODYNAMICS (PD):	PK-evaluable patients included randomized patients who received at least one dose of study drug and had provided at least one serum sample for the determination of omalizumab concentration. Blood samples were collected to determine serum omalizumab concentrations, free immunoglobulin E (IgE), and total IgE at Day 1 (predose), Week 12, Week 24 (end of treatment period) and Week 40 (end of follow-up period).
SAFETY:	The safety population included patients who received at least one dose of study drug. Safety was assessed through the summary of adverse events (AEs), laboratory test results, vital signs, and antibodies to omalizumab.
STATISTICAL METHODS	• Null hypothesis: no difference between the placebo group and each omalizumab group. • Unless otherwise specified, all analyses of efficacy outcomes from the treatment period were based on the mITT population. Patients were analyzed according to the treatment arm to which they were randomized. Treatment comparisons were performed between each of the omalizumab groups and the placebo group. Statistical tests were two sided using an overall 0.05 level of significance and adjustments for multiple comparisons were performed according to the type I error control plan using a hierarchical order • Analysis of the change from baseline in weekly itch severity score at Week 12 consisted of treatment comparisons between each of the omalizumab groups and the placebo group using analysis of covariance (ANCOVA), controlling for baseline weekly itch severity score (<13 vs. ≥ 13), and baseline weight (<80 kg vs. ≥ 80 kg). Missing Week 12 weekly itch severity scores were imputed by carrying forward the patients' baseline scores.

METHODOLOGY

The study consisted of three distinct periods over 42 weeks:

- Screening period: Day −14 to Day −1
- Treatment Period: Day 1 to Day 169 (Week 0 to Week 24)
- Follow up Period: Day 169 to Day 281 (Week 24 to Week 40)

For the screening period, patients were required to maintain stable doses of their prescreening H1 antihistamine treatment. To be eligible for the study, patients must have had no missing eDiary entries, an UAS7 $\geq$16 (equivalent to moderate to severe CIU symptoms for at least 4 out of the 7 days in a week), and a weekly itch severity score (UAS7 component) $\geq$8 for the 7 days prior to randomization.

On Day 1, eligible patients were randomly assigned (in a 1:1:1:1 ratio using an Interactive Voice and Web Response System [IxRS]) to receive omalizumab (75 mg, 150 mg, or 300 mg) or placebo by subcutaneous (SC) injection every 4 weeks during the 24 week double blind treatment period. Randomization to treatment groups was stratified by baseline weekly itch severity score, baseline weight, and study site. A hierarchical dynamic randomization scheme was used to achieve overall balance across treatment groups and within strata. Efficacy, safety, PK, and PD data were collected. The primary endpoint was measured at Week 12.

After the 24-week treatment period, all patients entered a 16-week follow up period to allow for further characterization of the PK and PD of omalizumab, collection of additional efficacy and safety data, and evaluation of the presence of anti-therapeutic antibodies (ATAs). Patients continued to visit the study center at 4 week intervals. No study treatment was given during the follow-up period.

On the basis of known/suspected drug administration effects, the following AEs were of special interest (AESI) with omalizumab treatment: anaphylaxis, Churg-Strauss Syndrome, hypersensitivity, injection-site reaction, malignancy, serum sickness syndrome, skin rash, thrombocytopenia and bleeding-related disorders, hematopoietic cytopenias, arterial thrombotic events, asthma/bronchospasm, and liver related investigations, signs and symptoms. AESI were identified by an ascertainment process based on a search of Medical Dictionary for Regulatory Activities (MedDRA) preferred terms, Standard MedDRA Query (SMQ) searches, or modified SMQ searches. In addition to SMQ searches, an ascertainment algorithm of preferred terms was used to select candidate patients with possible anaphylaxis and serum sickness syndrome for clinical adjudication. Suspected cases of anaphylaxis identified by the Sponsor were sent for blinded, external adjudication by the Anaphylaxis Review Committee.

EFFICACY RESULTS

The study met its primary efficacy endpoint with patients in each omalizumab dose group demonstrating statistically significant decreases from baseline in weekly itch severity scores at Week 12 relative to the placebo group. In addition, the following endpoints were met in the study by demonstrating statistically significant improvements in patients in the omalizumab groups (as specified below) compared with patients in the placebo group:

- All nine secondary efficacy endpoints for the 300-mg omalizumab group
- The first six secondary efficacy endpoints for the 150-mg omalizumab groups
- The first two secondary efficacy endpoints for the 75-mg omalizumab group

Greater efficacy was observed in the 300-mg omalizumab group relative to the 75 mg and 150 mg omalizumab groups for the primary endpoint and all of the secondary endpoints. The robustness of the results of the analysis of the primary efficacy endpoint was demonstrated by consistent results from subgroup and sensitivity analyses. The treatment benefit of omalizumab on itch severity was consistent across subgroups based on a wide range of patient characteristics. Results for most of the exploratory efficacy endpoints were consistent with the primary and secondary endpoints, in that they favored the omalizumab 300-mg group versus the placebo group.

A summary of key efficacy results is presented below. All p-values are relative to the placebo group.

Table 1 Summary of Key Efficacy Results: Modified Intent-to-Treat Population

	Placebo (n = 80)	Omalizumab 75 mg (n = 77)	Omalizumab 150 mg (n = 80)	Omalizumab 300 mg (n = 81)
Primary endpoint: Change from baseline to Week 12 in weekly itch severity score				
Mean (SD)	− 3.63 (5.22)	− 6.46 (6.14)	− 6.66 (6.28)	− 9.40 (5.73)
p-value (vs. placebo)	—	0.0010 [a]	0.0012 [a]	< 0.0001 [a]
Secondary endpoints (Presented as per hierarchical testing):				
Change from baseline to Week 12 in UAS7				
Mean (SD)	− 8.01 (11.47)	− 13.82 (13.26)	− 14.44 (12.95)	− 20.75 (12.17)
p-value (vs. placebo)	—	0.0035 [a]	0.0008 [a]	< 0.0001 [a]
Change from baseline to Week 12 in weekly number of hives score				
Mean (SD)	− 4.37 (6.60)	− 7.36 (7.52)	− 7.78 (7.08)	− 11.35 (7.25)
p-value (vs. placebo)	—	0.0149 [a]	0.0017 [a]	< 0.0001
Time to MID response in weekly itch severity score by Week 12				
Median (weeks)	4.0	3.0	2.0	1.0
HR	—	1.39	1.49	2.34
p-value (vs. placebo)	—	0.0879	0.0301 [a]	< 0.0001 [a]
Patients with UAS7 ≤ 6 at Week 12				
Number (%)	9 (11.3%)	20 (26.0%)	32 (40.0%)	42 (51.9%)
p-value (vs. placebo)	—	0.0148 [b]	< 0.0001 [a]	<0.0001 [a]
Proportion of weekly itch severity score MID responders at Week 12				
Number (%)	29 (36.3%)	43 (55.8%)	45 (56.3%)	61 (75.3%)
p-value (vs. placebo)	—	0.0118 [b]	0.0226 [a]	< 0.0001 [a]
Change from baseline to Week 12 in weekly size of largest hive score				
Mean (SD)	− 3.93 (5.44)	− 6.20 (6.29)	− 6.96 (6.68)	− 9.79 (6.66)
p-value (vs. placebo)	—	0.0124 [b]	0.0012 [a]	< 0.0001 [a]
Change from baseline in overall DLQI at Week 12				
Mean (SD)	− 6.13 (6.25)	− 6.33 (6.08)	− 8.00 (7.24)	− 10.29 (7.23)
p-value (vs. placebo)	—	0.7956 [b]	0.2286	< 0.0001 [a]
Proportion of angioedema free days from Week 4 to Week 12				
Mean (SD)	88.2% (19.4%)	86.5% (28.4%)	89.6% (20.6%)	96.1% (11.3%)
p-value (vs. placebo)	—	0.4867 [b]	0.1747 [b]	<0.0001 [a]
Proportion of Complete Responders (UAS7 = 0) at Week 12				
Mean (SD)	7 (8.8%)	9 (11.7%)	12 (15.0%)	29 (35.8%)
p-value (vs. placebo)	—	0.4580	0.2087 [b]	<0.0001 [a]

DLQI = Dermatology Life Quality Index; HR = hazard ratio; MID = minimally important difference; SD = standard deviation; UAS7 = urticaria activity score over 7 days.

[a] Statistically significant according to the type I error control plan.

[b] Not evaluated for statistical significance in accordance with the type I error control plan

PHARMACOKINETIC AND PHARMACODYNAMIC RESULTS

Following SC administration of omalizumab 75 mg, 150 mg, or 300 mg every 4 weeks, mean serum omalizumab concentrations at Week 12 and Week 24 increased proportionally with dose level. The concentrations at Week 24 were similar to those at Week 12 in patients for each dose group, suggesting that steady state was approached by Week 12. Mean serum free IgE levels were suppressed dose dependently from baseline to Week 12, remained stable from Week 12 to Week 24, and recovered toward baseline by the end of the follow-up period. Mean serum total IgE levels increased 2- to 3-fold from baseline to Week 12, remained stable from Week 12 to Week 24, and returned close to baseline by the end of the follow-up period.

Table 2 Mean (Standard Deviation) Serum Omalizumab, Free IgE and Total IgE Concentrations by Dose Group and Timepoint: Pharmacokinetic Evaluable Population

Analyte	Visit	Placebo	Omalizumab 75 mg	Omalizumab 150 mg	Omalizumab 300 mg
Omalizumab (μg/mL) Mean (SD)	Day1 (Predose)[a]	0.00801 (0.0568)	0.0297 (0.13)	0.00742 (0.0243)	0.00458 (0.026)
	Week 12	NR (NR)	7.41 (4.55)	13.3 (7.30)	30.6 (15.6)
	Week 24	NR (NR)	7.63 (4.20)	14.0 (8.79)	30.9 (15.3)
	Week 40	NR (NR)	0.346 (0.411)	1.96 (10.2)	2.01 (2.72)
Free IgE (IU/mL) Mean (SD)	Day1 (Predose)	NR (NR)	NR (NR)	NR (NR)	NR (NR)
	Week 12	NR (NR)	23.3 (21.6)	17.7 (18.2)	9.01 (10.2)
	Week 24	NR (NR)	24.8 (21.8)	19.3 (20.2)	8.11 (9.52)
	Week 40	NR (NR)	NR (NR)	NR (NR)	NR (NR)
Total IgE (IU/mL) Mean (SD)	Day1 (Predose)	161 (215)	203 (346)	216 (590)	153 (285)
	Week 12	166 (237)	444 (667)	461 (683)	508 (693)
	Week 24	179 (393)	464 (662)	533 (849)	470 (664)
	Week 40	153 (258)	209 (385)	262 (684)	206 (269)

LLOQ = lower limit of quantification; NR = non reportable; ULOQ = upper limit of quantification.

Notes: A result is NR when > 1/3 of the values are lower than reportable or > 1/3 of the values are greater than reportable. LLOQ: 0.028 μg/mL for omalizumab, 0.83 IU/mL for free IgE, 2 IU/mL for total IgE. ULOQ: none for omalizumab, 62.0 IU/mL for free IgE, 5000 IU/mL for total IgE.

Values less than reportable on Day 1 (predose) were set to 0.

SAFETY RESULTS

Omalizumab was well tolerated, and no new safety concerns aside from those already known with omalizumab use in patients with moderate to severe asthma were identified, as summarized below:

- During the treatment period, the proportions of patients who experienced at least one treatment-emergent AE was higher in the omalizumab group than the placebo group. The event types that account for the higher AE rate in the omalizumab groups were headaches, arthralgia, and injection-site reactions, which are events that are known to occur with omalizumab use in patients with moderate to severe asthma.

- The proportions of patients experiencing at least one AE suspected to be caused by study drug increased with increasing omalizumab dose. The majority of these AEs were mild or moderate in intensity.
- During the treatment period, 21 patients (6.6%) experienced a severe AE.
- No deaths occurred during the study.
- Among the AESI identified in this study, three patients were identified by the Sponsor as suspected cases of anaphylaxis and submitted for blinded, external adjudication. Two of the three suspected cases were externally adjudicated as anaphylaxis: one not related to study drug and one related to dipyrone.
- One patient in the placebo group experienced an event of cervical dysplasia which was determined to be cervical adenocarcinoma in situ post-database lock.
- During the treatment period, 9 patients (2.8%) experienced a serious adverse event (SAE). None of the reported SAEs were assessed by the investigator to be related to study drug.
- During the follow-up period, 5 patients (1.6%) experienced at least one SAE. None of the reported SAEs were assessed by the investigator to be related to study drug.
- Fifteen patients (4.7%) experienced a treatment-emergent AE that led to withdrawal of study drug.
- Five patients (1.6%) withdrew from the study because of a treatment-emergent AE.
- For all hematology lab parameters, no notable changes or major differences across treatment groups were observed in the values assessed.

Table 3 Overview of Patients with Adverse Events: Safety Evaluable Patients

	Placebo (n = 80)	Omalizumab 75 mg (n = 70)	Omalizumab 150 mg (n = 87)	Omalizumab 300 mg (n = 81)	All Patients (n = 318)
Any AE during treatment period	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
AE suspected to be caused by study drug	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
Severe AE during treatment period	8 (10.0%)	5 (7.1%)	5 (5.7%)	3 (3.7%)	21 (6.6%)
Deaths	0	0	0	0	0
SAEs during treatment period	4 (5.0%)	2 (2.9%)	3 (3.4%)	(0.0%)	9 (2.8%)
SAEs during follow-up	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
Withdrawal from study due to AE	2 (2.5%)	0	2 (2.3%)	1 (.2%)	5 (1.6%)
AE leading to withdrawal from treatment	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)

AE = adverse event; SAE = serious adverse event.

CONCLUSIONS

Omalizumab therapy in adolescent and adult patients aged 12–75 years with refractory CIU receiving concomitant approved doses of H1 antihistamine in this global, Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study demonstrated significant clinical benefits and no new safety concerns as supported by the following conclusions:

- Statistically significant effects conferring therapeutic benefits were observed in the omalizumab 75-mg, 150-mg, and 300-mg groups for the primary efficacy endpoint.
- All nine secondary efficacy endpoints were met in the omalizumab 300-mg group compared with the placebo group. The first six secondary efficacy endpoints were met in the omalizumab 150-mg group compared with the placebo. The first two secondary efficacy endpoints were met in the omalizumab 75-mg group compared with the placebo group.
- The robustness of the primary efficacy results was supported by consistent findings from the sensitivity and subgroup analyses.
- Patients in the omalizumab groups had a rapid onset of treatment effect, and after Week 24 (follow-up period), mean symptom scores increased to reach values similar to mean placebo group values and neither the placebo group nor any of the omalizumab groups returned to the baseline values for the duration of the follow-up period.
- A dose response was observed with the efficacy results. For all the secondary efficacy endpoints, the 300-mg omalizumab group demonstrated the greatest efficacy relative to the placebo group at Week 12.
- Compared to the placebo group, a statistically significant improvement in health-related quality of life was observed for patients in the 300-mg omalizumab group as reflected by a greater decrease from baseline in overall DLQI score.
- The difference between the omalizumab 300-mg and the placebo groups in mean proportion of angioedema-free days from Week 4 to Week 12 was statistically significant in favor of omalizumab ($p < 0.0001$).
- The incidence of common treatment-emergent AEs during the treatment period was higher in the omalizumab group (57 to 69%) than the placebo group (51%) and the majority of these events were mild or moderate in intensity. During the treatment period, the event types that account for the higher AE rate in the omalizumab groups were events known to occur with omalizumab use in patients with moderate to severe asthma.
- While on study, the overall proportion of patients with reported treatment-emergent SAEs was 4.4% of all patients, and the SAE rate was numerically lower in the omalizumab groups than in the placebo group. No deaths occurred.
- Three suspected cases of anaphylaxis were identified by the Sponsor and submitted for blinded, external adjudication and the results of this adjudication are: two cases were assessed as an anaphylaxis event not related to study drug and one case was assessed as not an anaphylaxis event.
- Omalizumab was generally well tolerated and did not result in new or clinically significant safety concerns in patients with refractory CIU. The AEs were consistent either with the known omalizumab safety profile in allergic asthma patients or with those CIU-related events observed in the placebo group of this study.

CORE REPORT

GLOSSARY OF ABBREVIATIONS

AE	adverse event
AESI	adverse event of special interest
ALT	alanine aminotransferase
ANCOVA	analysis of covariance
AST	aspartate transaminase
ATA	anti-therapeutic antibody
ATE	arterial thrombotic event
BAR	bioanalytical report
BMI	body mass index
BOCF	baseline-carry-forward
CI	confidence interval
CIU	chronic idiopathic urticaria
CMH	Cochran-Mantel-Haenszel
COPD	chronic obstructive pulmonary disease
CSR	clinical study report
CSU	chronic spontaneous urticaria
CU	chronic urticaria
CU-Q2oL	Chronic Urticaria Quality-of-Life Questionnaire
DBP	diastolic blood pressure
DLQI	Dermatology Life Quality Index
eCRF	Case Report Form

GLOSSARY OF ABBREVIATIONS

eDiary	electronic diary
EQ-5D	EuroQoL-5D
FcεRI	high-affinity immunoglobulin E receptors
FDA	Food and Drug Administration
FSH	follicle stimulating hormone
GCP	Good Clinical Practice
GERD	gastroesophageal reflux disease
GI	gastrointestinal
HCG	urine-human chorionic gonadotropin
HCU	Healthcare utilization
HPF	high power field
ICF	informed consent forms
ICH	International Conference on Harmonisation
iDCC	independent Data Coordinating Center
iDMC	independent Data Monitoring Committee
IEC	Institutional Ethics Committee
IgE	immunoglobulin E
IND	Investigational New Drug Application
IRB	Institutional Review Board
IUD	intrauterine device
IVIG	IV immunoglobulin G
IxRS	interactive voice and web response system

GLOSSARY OF ABBREVIATIONS

LLN	lower limit of normal
LLOQ	lower limit of quantification
LOCF	last observation carry forward
LS(M)	least squares (mean)
LTRA	leukotriene receptor antagonist
MAO	monoamine oxidase
MedDRA	Medical Dictionary for Regulatory Activities
MESF	Molecules of equivalent, soluble fluorochrome units
MID	minimally important difference
mITT	modified intention to treat
MOS	Medical Outcomes Study
NEC	Not elsewhere classifiable
PD	pharmacodynamic
PH	proportional hazards
PK	pharmacokinetic
POC	proof of concept
PRO	patient reported outcome
QD	once per day
RBC	red blood cells
RNA	ribonucleic acid
ROR	reporting odds ratio
SAE	serious adverse event

GLOSSARY OF ABBREVIATIONS

SAP	statistical analysis plan
SBP	systolic blood pressure
SC	subcutaneous
SD	standard deviation
SMQ	Standard MedDRA Query
SOC	system organ class
SOP	standard operating procedure
SWFI	Sterile Water for Injection
UAS	urticaria activity score
UAS7	urticaria activity score over 7 days
UPDD	Urticaria Patient Daily Diary
USP	United States Pharmacopeia
WBC	white blood cells

1. INTRODUCTION

Chronic idiopathic urticaria (CIU) is defined as the spontaneous occurrence of daily, or almost daily, hives and itching for at least 6 weeks without an obvious cause (Greaves 2003). CIU can also be referred to as chronic spontaneous urticaria (CSU) as shown in recent guidelines adopted by European and global allergy and dermatology associations (Zuberbier et al. 2009). In this document, the term CIU will be used to refer to the disease of interest and should be read as interchangeable with CSU. In clinical practice, H1 antihistamine therapy is used as first-line CIU treatment based on data from randomized controlled pivotal trials up to 6 weeks (Kozel et al. 2001). However, specialty clinic surveys have suggested that beyond 6 weeks H1 antihistamine efficacy diminishes and by 12 weeks more than 86% of patients with CIU do not demonstrate a complete response (i.e., symptom free) (Kozel et al. 2001). Because H1 antihistamines exhibit only modest efficacy over longer intervals, immunosuppressants and plasmapheresis are used in the treatment of patients with CIU. In the placebo arm of a cyclosporine trial (treatment with H1 antihistamine cetirizine only allowed), patients exhibited only modest 23% and 25% severity score improvement from baseline by Weeks 8 and 16, respectively, compared with 63% and 53% improvement from baseline with cyclosporine (Vena et al. 2006). However, such potent immunosuppressive treatments carry a substantial risk of significant life-threatening adverse effects (Kozel and Sabroe 2004). Symptoms of CIU exert a profound negative influence on a patient's quality of life (Tilles 2005); thus, the lack of efficacious therapies represents a significant unmet need for these patients.

The etiology of CIU is unclear; theories have included an infectious origin, while the preponderance of opinion has favored an autoimmune origin (Fiebiger et al. 1995; Tong et al. 1997; Zweiman et al. 1998; Fukuda et al. 2004). Some studies have reported that 30%–60% of patients with CIU have an autoimmune component (Fiebiger et al. 1995; Tong et al. 1997; Zweiman et al. 1998; Shakouri et al. 2010). In patients suspected of having an autoimmune etiology for their CIU, it is thought that symptoms result from mediator release following the cross-linking of high-affinity immunoglobulin E (IgE) receptors (FcεRI) on mast cells and basophils. Anti-IgE antibodies and functional antibodies against the alpha chain of the high-affinity IgE receptor found on mast cells, basophils, and antigen-presenting cells have been isolated from the serum of patients with CIU (Grattan 1991; Hide et al. 1993; Niimi et al. 1996).

Xolair® (omalizumab) is a humanized anti-IgE recombinant monoclonal antibody approved to treat allergic asthma. Omalizumab works by inhibiting binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils. Reduction of surface-bound IgE on cells expressing FcεRI limits the degree of release of mediators in the allergic response. Omalizumab treatment in patients with asthma has been reported to effect a decrease in free IgE levels of 89%–98% (Slavin et al. 2009). The decrease in free IgE levels results in down-regulation of FcεRI expression on basophils and mast cells, which confers cellular resistance to other releasing factors. Given the association

of IgE high-affinity receptor activation, mediator release, and CIU, several studies were conducted to determine whether omalizumab could be a useful therapy for this disease (Gober et al. 2008).

Data from these small early studies suggested that omalizumab improved urticaria and pruritus in patients with CIU who had failed H1 antihistamine treatment, as well as in those who had failed treatment with a combination of H1 and H2 antihistamines and a leukotriene receptor antagonist (Gober et al. 2008; Kaplan et al. 2008). Subsequently, the Sponsor undertook a larger Phase II proof-of-concept (POC) study (Study Q4577g), and data from this study demonstrated that a single dose of omalizumab at either 300 mg or 600 mg significantly improved efficacy outcomes, including pruritus, at Week 4 with no new safety signals compared with what is observed in omalizumab-treated patients with moderate to severe asthma. Pruritus is the most important and bothersome symptom that patients with CIU report, and it has a significant impact on their health-related quality of life (Mathias et al. 2010, 2012).For more details on these studies, see Section 1.2.2 of the protocol on page 1420. To further evaluate the safety and efficacy of omalizumab in patients with refractory CIU, this Phase III study was designed to evaluate the effect of omalizumab in patients with CIU who remain symptomatic despite treatment with H1 antihistamines.

2. OBJECTIVES

2.1 PRIMARY OBJECTIVE

The primary objective of this study was to evaluate the efficacy of omalizumab compared with placebo in patients with refractory CIU receiving concomitant H1 antihistamine therapy.

2.2 SECONDARY OBJECTIVES

The secondary objectives for this study were as follows:

- To evaluate the safety of omalizumab therapy in patients with refractory CIU
- To evaluate onset of clinical effect of omalizumab therapy in CIU
- To evaluate the dose of omalizumab therapy in patients with refractory CIU
- To evaluate duration of response after withdrawal of omalizumab in patients with refractory CIU
- To evaluate the quality-of-life benefit of omalizumab therapy in patients with refractory CIU

3. MATERIALS AND METHODS

3.1 OVERALL STUDY DESIGN

Study Q4881g (ASTERIA I) was a global, Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of omalizumab administered subcutaneously as an add-on therapy for the treatment of

adolescent and adult patients aged 12–75 who have been diagnosed with refractory CIU and who remain symptomatic despite standard-dosed H1 antihistamine treatment. Approximately 300 patients were planned for enrollment at approximately 70 study sites globally.

The study consisted of three distinct periods over 42 weeks (see also Figure 1):

- Screening period: Day −14 to Day −1
- Treatment Period: Day 1 to Day 169 (Week 0 to Week 24)
- Follow-up Period: Day 169 to Day 281 (Week 24 to Week 40)

The screening period consisted of visits at Day −14 and Day −7. Patients were required to meet all of the following criteria to enter the screening period:

- Non-electronic diary-based urticaria activity score (UAS) ≥4 established in the clinic based on the patient's condition over 12 hours prior to either Day −14, Day −7, or Day 1, despite being on H1 antihistamine therapy
- Use of an approved dose of an H1 antihistamine for treatment of CIU at Day −14 and for at least the 3 consecutive days immediately prior to Day −14
- Willing and able to complete an electronic symptom diary twice daily throughout the screening period to establish the patient's UAS score

Patients completed the 2-week screening period to establish their eligibility for the study and to capture baseline symptom scores. For the duration of the screening period, patients were required to maintain stable doses of their pre-screening H1 antihistamine treatment. To be eligible for the study, patients must have had no missing electronic diary (eDiary) entries, an urticaria activity score over 7 days (UAS7) symptom score of ≥16 (equivalent to moderate to severe CIU symptoms for at least 4 out of the 7 days in a week), and a weekly itch severity score (a component of the UAS7) of ≥8 for the 7 days prior to randomization.

Only in exceptional circumstances, when information concerning eligibility was outstanding (e.g., pending laboratory data), was an extended screening period permitted. Upon approval from the Medical Monitor, patients were re-screened. Circumstances that permitted re-screening included, but were not limited to, an in-clinic UAS score or laboratory test result that did not meet eligibility requirements.

On Day 1, eligible patients were randomly assigned (in a 1:1:1:1 ratio using an Interactive Voice and Web Response System [IxRS]) to receive omalizumab (75 mg, 150 mg, or 300 mg) or placebo by subcutaneous (SC) injection every 4 weeks during the 24-week double-blind treatment period. Approximately 75 patients were to be randomized to each of the 75 mg, 150 mg, and 300 mg omalizumab treatment and placebo arms. Randomization to treatment groups was stratified by baseline weekly itch severity score, baseline weight, and study site. A hierarchical dynamic randomization scheme was used to achieve overall balance across treatment groups and within strata.

Efficacy, safety, pharmacokinetic (PK), and pharmacodynamic (PD) data were collected. The last dose of study drug was administered at the Day 141 (Week 20) study visit. The primary endpoint was measured at Week 12. For the first 12 weeks of the treatment period, patients were required to maintain stable doses of their pre-randomization H1 antihistamine treatment. During the second 12 weeks of the treatment period, patients could add up to one additional H1 antihistamine treatment. Increasing the dose of antihistamine above the approved dose was not permitted.

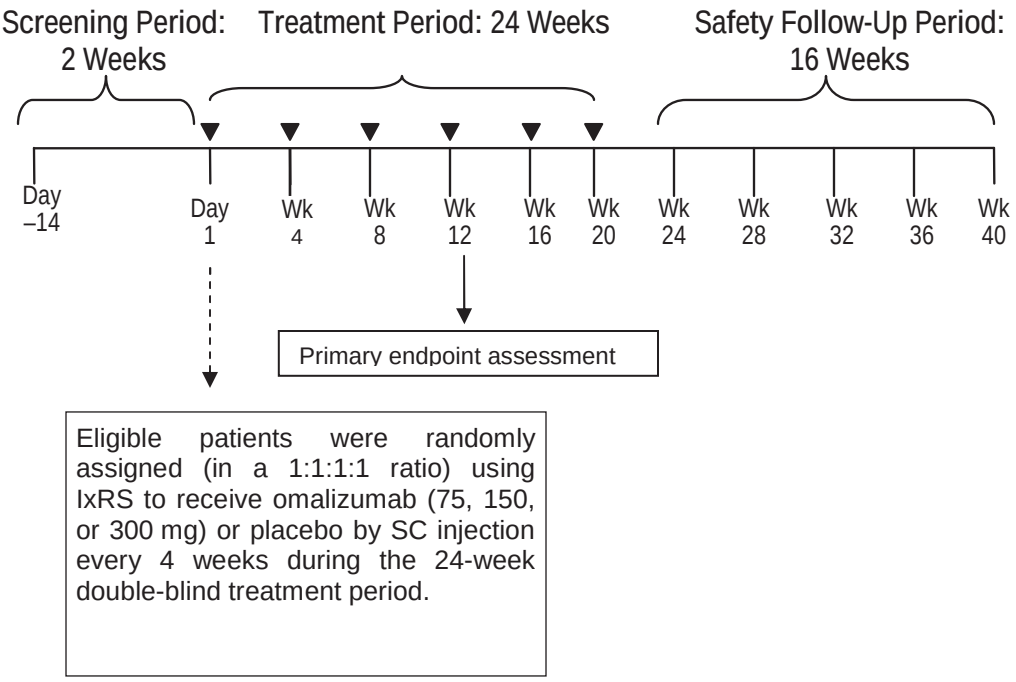
After completion of the 24-week treatment period, all patients entered a 16-week follow-up period to allow for further characterization of the PK and PD of omalizumab, collection of additional efficacy and safety data, and evaluation of the presence of anti-therapeutic antibodies (ATAs). Patients continued to visit the study center at 4-week intervals. No study drug treatment was given during the follow-up period. The end of the study was defined as the last enrolled patient's last visit.

The blind was maintained for the full 40 weeks of the study (post-randomization). For the duration of the study, all patients were provided diphenhydramine (25 mg) for itch relief on an as-needed basis (up to a maximum of three doses in 24 hours or less based on local regulations).

An independent Data Monitoring Committee (iDMC) was established to monitor safety and study conduct. Members of the iDMC were external to the Sponsor, and met at regular intervals (at least once every 6 months) up until the end of the study.

The protocol and all amendments are provided on page 1398. A sample electronic Case Report Form (eCRF) is provided on page 1599. Sample informed consent forms (ICFs) are provided on page 1553 and page 1556, (U.S. Child Assent); page 1535, page 1503 and page 1519 (Ex-U.S. and E.U.); and on page 1589, page 1573 and page 1558 (U.S.).

Figure 1 Study Schema



IxRS = interactive voice and web response system; SC = subcutaneous; Wk = week.

3.2 DISCUSSION OF STUDY DESIGN

The objective of this Phase III study was to evaluate the efficacy and safety of omalizumab dosed every 4 weeks in patients with CIU refractory to non-sedating H1 antihistamines at approved doses as demonstrated by the presence of itch and hives for ≥ 8 consecutive weeks at any time prior to enrollment. This study evaluated the comparative efficacy between omalizumab and placebo as well as the time to onset of clinical effect for patients with CIU refractory to non-sedating H1 antihistamine therapy. The doses for this study were selected based on the efficacy results from Studies CIGE025ADE05 and Q4577g.

Efficacy was determined using the primary endpoint of change from baseline in the weekly itch severity score (a component of the UAS7) at Week 12. Weekly itch severity was selected for this assessment, as it is the symptom of greatest concern to patients, with greatest impact on their quality of life (Mathias et al. 2010).

As CIU symptoms are composed chiefly of hives and intense itch, the evaluation of clinical response through use of the UAS, a composite endpoint that measures both of these symptoms, was considered appropriate. UAS7 was therefore incorporated as a secondary endpoint.

Time to onset of the clinical effect of treatment with omalizumab was evaluated during the treatment period. Time to onset of clinical effect is important to establish so that guidance may be given to patients with regards to when a response should be expected as well as a period of time beyond which a minimal, if any, clinical response is expected to occur.

Symptom recurrence after study drug was withdrawn at Week 24 was assessed up to Week 40. For all patients, symptom scores were measured during both the treatment and follow-up periods. Patients treated with omalizumab who had a clinical response (UAS7 $\leq$ 6) at Week 24 were evaluated for symptom relapse. This information will be used, along with data from other studies with different treatment durations, to provide guidance for the duration of therapy.

3.3 ADMINISTRATIVE STRUCTURE AND STUDY CONDUCT

3.3.1 Study Administrative Structure

Omalizumab in the treatment of CIU is a joint development project between Genentech, Inc., and Novartis Pharma AG. This study was sponsored by Genentech, Inc., and managed by Genentech and Quintiles, Inc. as described in Table 1. Genentech, Inc. is the holder of the U.S. Investigational New Drug Application (IND) under which this study was conducted. Quintiles, Inc. filed clinical trial applications and ethics committee submissions for this study outside of the U.S., as appropriate.

An iDMC was convened to evaluate the safety data at 6-month intervals; members of the iDMC were external to the Sponsor. This committee consisted of one biostatistician and two clinicians experienced in treating patients with CIU. A separate Anaphylaxis Review Committee comprised of external experts in CIU and anaphylaxis (two adjudicators and one chairman) was convened to clinically review anaphylaxis cases in a blinded fashion. The assembly of the Anaphylaxis Review Committee was not planned at the beginning of the study but was established close to the completion of the study.

The investigators and their addresses are listed on page 1783.

Table 1 Study Administrative Structure

Role/Responsibility	Company/Organization
Clinical Study Management, Data Handling and Logistic Services	[redacted]
Archiving of Trial Master File	[redacted]
Drug Supply	[redacted]
Drug Product Manufacture	[redacted]
Drug Substance Manufacture	[redacted]
Drug Depot and Release (Europe)	[redacted]
Laboratory Sample Shipment	[redacted]
Central Laboratories	[redacted]
PK, PD, ATA, Free IgE Analysis	[redacted]
Basophil, FcεR1 Expression	[redacted]

Table 1 Study Administrative Structure (cont.)

Role/Responsibility	Company/Organization
Total IgE Analysis, CU Index Testing	[redacted]
IxRS	[redacted]
Principal Investigator	[redacted]
Statistical Analysis	[redacted]
Data Management	[redacted]
Medical Writing	[redacted]

ATA = Anti Therapeutic Antibody; CU = Chronic Urticaria; Ige = Immunoglobulin E; PD = Pharmacodynamics; PK = Pharmacokinetic; Ixrs = Interactive Voice And Web Response System

Note: For a list of investigators see page 1783. For a list of laboratories see page 1834.

3.3.2 Ethics and Study Conduct

This study was conducted in accordance with the U.S. Food and Drug Administration (FDA) regulations, the International Conference on Harmonisation (ICH) E6 Guideline for Good Clinical Practice (GCP), Declaration of Helsinki, and applicable local, state, and federal laws, as well as other applicable country laws. Other aspects of study conduct are summarized in Table 2.

For ex-U.S. sites the following was ensured:

- Investigators were trained in GCP according to Genentech and Quintiles, Inc. standard operating procedures (SOPs)
- Written commitment from investigators to comply with GCP was obtained
- Approval from the independent ethics committee/ institutional review board (IEC/IRB) was obtained before study start and prior to implementation of any protocol

amendments. This was documented in correspondence to the Investigator specifying the date on which the committee met and granted the approval. Genentech also obtained approval from the relevant Competent Authority prior to starting the study. There was one amendment to the protocol on 11 January 2011.

All patients received standard of care H1 antihistamine treatment at approved doses. In addition, all patients were provided additional diphenhydramine treatment on an as-needed basis. Necessary precautions were taken to ensure patient safety.

Table 2 Study Conduct Details

	Protocol Section/Appendix
Data quality assurance and data collection and management	Protocol, Section 4.11 page 1457 Audit certificate is provided on page 1808
Compliance with laws and regulations	Protocol, Section 3.10 page 1436
Informed consent procedures	Protocol, Section 6.1 page 1469 Protocol, Section 6.3 page 1470 Sample informed consent forms on page 1553 and page 1556, (U.S. Child Assent); page 1535, page 1503 and page 1519 (Ex-U.S. and E.U.); and on page 1589, page 1558 and page 1573 (U.S.).
Institutional Review Boards and/or Ethics Committee approval	Protocol, Section 6.1 page 1469 Protocol, Section 6.2 page 1470 List of IRBs/IECs is provided on page 1789

The Roche Clinical Quality Assurance group or designee conducted audits at four investigator sites. No critical audit findings were observed. Appropriate corrective and preventive actions were undertaken for all audit findings. The audit certificate is provided on page 1808.

3.4 SELECTION OF STUDY POPULATION

This study enrolled patients diagnosed with refractory CIU who remained symptomatic despite conventional H1 antihistamine treatment.

3.4.1 Inclusion Criteria

Patients must have met the following criteria for study entry:

1. Aged 12–75 years (age limits may vary dependent upon regional restrictions)
2. Diagnosis of CIU refractory to approved doses of H1 antihistamines at the time of randomization, as defined by all of the following:

   The presence of itch and hives for ≥8 consecutive weeks at any time prior to enrollment despite current use of H1 antihistamine treatment during this time period

   UAS7 score (range 0–42) ≥16 and itch component of UAS7 (range 0–21) ≥8 during 7 days prior to randomization (Week 0)

In-clinic UAS ≥ 4 on at least one of the screening visit days (Day -14, Day -7, or Day 1)

Patients must have been on an approved dose of an H1 antihistamine for CIU for at least the 3 consecutive days immediately prior to the Day -14 screening visit and must have documented current use on the day of the initial screening visit

CIU diagnosis for ≥ 6 months

3. Willing to give written informed consent, adhere to the visit schedules and meet study requirements

   For those patients below the legal age of consent, the child must have been willing to give written informed assent and the parent(s)/guardian(s) must have been willing to give written informed consent.

   For patients below the legal age of consent, both child and parent must have been able to adhere to dose and visit schedules and met study requirements.

4. Willing and able to complete a daily symptom eDiary for the duration of the study
5. Patients must not have had any missing eDiary entries in the 7 days prior to randomization

3.4.2 Exclusion Criteria

Patients who met any of the following criteria were excluded from study entry:

1. Treatment with an investigational agent within 30 days of Day -14
2. Weight less than 20 kg (44 lbs)
3. Clearly defined underlying etiology for chronic urticarias other than CIU (main manifestation being physical urticaria). This included the following urticarias:

   Acute, solar, cholinergic, heat, cold, aquagenic, delayed pressure or contact

   As well as the following diseases as these diseases may have symptoms of urticaria or angioedema:

   Urticarial vasculitis, urticaria pigmentosa, erythema multiforme, mastocytosis, hereditary or acquired angioedema, lymphoma, leukemia, or generalized cancer

6. Evidence of parasitic infection defined as having the following three items:

   Risk factors for parasitic disease (living in an endemic area, chronic gastrointestinal [GI] symptoms, travel within the last 6 months to an endemic area and/or chronic immunosuppression)

   AND

   An absolute eosinophil count more than twice the upper limit of normal

   AND

   Evidence of parasitic colonization or infection on stool evaluation for ova and parasites. Note that stool ova and parasite evaluation are conducted in patients with both risk factors and an eosinophil count more than twice the upper limit of normal

7. Atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, or other skin disease associated with itch
8. Previous treatment with omalizumab within a year prior to Day −14
9. Routine (daily or every other day during 5 or more consecutive days) doses of the following medications within 30 days prior to Day −14: systemic or cutaneous (topical) corticosteroids (prescription or over the counter), hydroxychloroquine, methotrexate, cyclosporine, or cyclophosphamide
10. IV immunoglobulin G (IVIG), or plasmapheresis within 30 days prior to Day −14
11. Regular (daily or every other day) doxepin (oral) use within 14 days prior to Day −14
12. Any H2 antihistamine used within 7 days prior to Day −14
13. Any leukotriene receptor antagonist (LTRA) (montelukast or zafirlukast) within 7 days prior to Day −14
14. Any H1 antihistamines at greater than approved doses within 3 days prior to Day −14
15. Patients with current malignancy, history of malignancy, or currently under work-up for suspected malignancy, except non-melanoma skin cancer that was treated or excised and considered resolved.
16. Hypersensitivity to omalizumab or any component of the formulation
17. History of anaphylactic shock
18. Presence of clinically significant cardiovascular, neurological, psychiatric, metabolic, or other pathological conditions that could interfere with the interpretation of the study results and or compromise the safety of the patients
19. Medical examination or laboratory findings that suggest the possibility of decompensation of co-existing conditions for the duration of the study. Any items that are cause for uncertainty were reviewed with the Medical Monitor.
20. Inability to comply with study and follow-up procedures
21. Evidence of current drug or alcohol abuse
22. Nursing women or women of childbearing potential, defined as all women physiologically capable of becoming pregnant, including women whose career, lifestyle, or sexual orientation precludes intercourse with a male partner and women whose partners have been sterilized by vasectomy or other means, unless they met the following definition of post-menopausal: 12 months of natural (spontaneous) amenorrhea or 6 months of spontaneous amenorrhea with serum follicle stimulating hormone (FSH) levels >40 m IU/mL or 6 weeks post-surgical bilateral oophorectomy (with or without hysterectomy) or hysterectomy or are using one or more of the following acceptable methods of contraception: surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: intrauterine device [IUD], male or female condom with spermicidal gel, diaphragm, sponge, or cervical cap).

23. Contraindications to diphenhydramine: Over reactivity against the agent diphenhydramine, other antihistaminic agents, or other components of this agent; acute bronchial asthma; acute angle-closure glaucoma; pheochromocytoma; hyperplasia of the prostate gland with formation of residual urine; epilepsy; hypokalemia; hypomagnesemia; bradycardia; a congenital long QT syndrome or other clinically significant cardiac disorders (especially coronary heart disease, disturbances in conduction, arrhythmias); the simultaneous application of drugs which prolong the QT interval (e.g., antiarrhythmic drugs Class IA or III, antibiotics, cisapride, malaria drugs, antihistaminic drugs, neuroleptic drugs) or led to hypokalemia (e.g., certain diuretic drugs); the simultaneous application of monoamine oxidase (MAO) inhibitors; the simultaneous uptake of alcohol

3.5 STUDY TREATMENTS

3.5.1 Dosage and Administration

Patients received omalizumab (75 mg, 150 mg or 300 mg) or placebo administered subcutaneously every 4 weeks at the study center. Missed doses were not replaced.

Study drug was supplied as a lyophilized, sterile powder in a single-use, 5-mL vial that was designed to deliver 150 mg of omalizumab or placebo for SC administration upon reconstitution with 1.4 mL Sterile Water for Injection (SWFI).

Each patient received two injections of study drug or placebo at every treatment visit. For details regarding each individual's injection, please refer to Appendix F of the protocol on page 1498.Doses of more than 150 mg were divided among multiple injection sites to limit injections to not more than 150 mg per site. For further details on the dosage and administration of omalizumab see Section 4.3.1 of the protocol on page 1440.

The long-acting H1 antihistamines and doses allowed during the study were as follows:

- Cetirizine 5 or 10 mg once per day (QD)
- Levocetirizine dihydrochloride 2.5 or 5 mg QD
- Fexofenadine 60 mg twice per day or 180 mg QD
- Loratadine 10 mg QD
- Desloratadine 5 mg QD

Inadvertently, the following medications were omitted from the protocol's list of allowable H1 antihistamines:

- Ebastine 10 mg and 20 mg QD
- Rupatadine 10 mg QD
- Bilastine 20 mg QD

Genentech, through the decision of the Medical Monitor after the first patient was enrolled, granted permission for patients to receive ebastine, rupatadine, or bilastine medications from 10 May 2011 onward. These medications had been approved for use

in the countries outside the United States where the study was conducted. Thus these were appropriate H1 antihistamines, if taken at the indicated frequency and dose levels noted above. Protocol violations have been documented for all patients who received these medications.

3.5.2 Formulation and Packaging

Omalizumab was provided as a sterile, white, preservative-free, lyophilized powder, contained in a single-use vial that was reconstituted with SWFI, United States Pharmacopeia (USP), and administered as a SC injection. Each omalizumab vial contains 202.5 mg omalizumab, 145.5 mg sucrose, 2.8 mg L-histidine hydrochloride monohydrate, 1.8 mg L-histidine, and 0.5 mg polysorbate 20. Each vial was designed to deliver 150 mg of omalizumab in 1.2 mL after reconstitution with 1.4 mL SWFI, USP.

Study drug was packaged in boxes of 1 vial per box, and two boxes were provided at each dosing visit for the patient.

The placebo contained the same ingredients as the omalizumab formulation listed above, excluding omalizumab. Please refer to the Study Q4881g protocol on page 1440 for additional details regarding the storage of omalizumab. The lot numbers for omalizumab 150 mg used in this study were: [redacted] and [redacted]; the lot numbers for the placebo were: [redacted] and [redacted] (see page 1833).

3.5.3 Rationale for Dosage Selection

The doses for this study were selected on the basis of the results of both the Phase II Study Q4577g that tested a range of omalizumab doses (75 mg, 300 mg, and 600 mg) as a single SC injection in patients with CIU refractory to H1 antihistamines and the company-sponsored Study CIGE025ADE05 that tested omalizumab dosed at 75 to 375 mg according to the patient's baseline IgE levels and body weight.

To determine the appropriate dose of omalizumab for patients with CIU refractory to H1 antihistamines, three dose levels of omalizumab (75 mg, 150 mg, and 300 mg) given every 4 weeks were evaluated during the treatment period in order to better define the dose-response relationship between omalizumab and a reduction of CIU symptoms. The highest dose level was set to 300 mg because the results from Study Q4577g suggested an efficacy plateau might have been reached at this dose level when given as a single dose. Additionally, the lowest dose level of 75 mg was included to evaluate whether efficacy is achieved at this level with multiple dosing, given that a single dose at 75 mg was not effective in Study Q4577g. Finally, an intermediate dose level of 150 mg was tested to better characterize the dose-response relationship suggested by Study CIGE025ADE05. Fixed dosing for each treatment arm was used in the current study because the results from Study Q4577g showed no clear relationship between efficacy, measured through UAS7, and body weight or baseline IgE level. An effect of body weight on systemic exposure to omalizumab was observed as expected. The time at which peak efficacy was observed in Study Q4577g defined the dosing interval of

once every 4 weeks to minimize breakthrough CIU symptoms while avoiding the need to give omalizumab more frequently than necessary. For more details on Studies Q4577g and CIGE025ADE05 see Section 3.2.1 of the Study Q4881g protocol on page 1428.

3.5.4 Method of Treatment Assignment

On the Day 1 visit, patients were randomized to one of 3 doses of omalizumab (75 mg, 150 mg, or 300 mg) or placebo at an approximately 1:1:1:1 ratio using an IxRS. Randomization to treatment groups was stratified by baseline weekly itch severity score, baseline weight, and study site. A hierarchical dynamic randomization scheme was used to achieve overall balance across treatment groups and within strata. Detailed specifications of the dynamic randomization scheme can be found on page 1769.

3.5.5 Blinding

This was a blinded study. Patients, all study personnel, the designated evaluating physician(s), the Sponsor and its agents (with the exception of the IxRS service provider, the remote unblinded monitoring staff, the unblinding statistician, the unblinded pharmacists at the sites, the iDMC members and the independent Data Coordinating Center [iDCC] personnel) were blinded to treatment assignment. Only the IxRS provider, the Sponsor's unblinding statistician, and the iDCC statistician had access to the unblinding code during the study.

Study drug supplies were shipped blinded to each site. Each center identified an individual responsible (e.g., pharmacist) for the reconstitution procedures. This individual prepared the study drug for each patient prior to administration. An individual not involved with evaluating the patient was identified to administer the study drug. To minimize the risk of potential bias arising from access to laboratory results that could potentially unblind treatment assignments (e.g., free IgE levels and serum omalizumab concentrations), access to these results were withheld from the site and the Sponsor until study completion.

During the conduct of the study, a treatment assignment was unblinded only in the event of a life-threatening medical emergency that required immediate unblinding/unmasking, or in the event of an unexpected serious adverse event (SAE) judged by the investigator as related to study drug, or for FDA safety reporting. In such cases, unblinding was implemented following standard procedures and only following agreement by both the investigator and Medical Monitor that unblinding was necessary. There were no treatment assignment unblindings during the study.

Unblinded safety data, as well as unblinded baseline characteristics and protocol deviation data were provided directly to the iDMC by the iDCC (see Section 5.5.3 for more information).

3.5.6 Criteria for Dose Modification or Withdrawal from Treatment

No dose modification of study drug was allowed during this study. The investigator had the right to discontinue a patient from study treatment for any medical condition that the investigator determined could jeopardize the patient's safety if he or she continued in the study; for reasons of noncompliance (e.g., missed doses, missed visits, or missing eDiary entries); if the patient became pregnant; or if the investigator determined it was in the best interest of the patient.

Patients who received any excluded therapy (see Section 4.4.2 of the protocol on page 1443) after randomization were discontinued from study treatment (with the exception of patients who received H1 antihistamines approved for use in the countries outside the United States where the study was conducted. These antihistamines were originally identified as excluded therapy; for more information see Section 3.5.1); if a patient had received at least one dose of study drug following enrollment, the patient was monitored for safety for the remainder of the study.

3.5.7 Treatment Accountability and Compliance

All study drug required for completion of this study was provided by the Sponsor. The recipient acknowledged receipt of the drug by returning the appropriate documentation form indicating shipment content and condition. Damaged supplies were replaced. Accurate records of all study drug received at, dispensed from, returned to and disposed of by the study site was recorded by using the Drug Inventory Log. Study drug was either disposed of at the study site according to the study site's institutional SOP or returned to Sponsor or designee with the appropriate documentation, as determined by the study site.

If the study site chose to destroy study drug, the method of destruction was documented. Sponsor or designee evaluated and approved the study site's drug destruction SOP prior to the initiation of drug destruction by the study site.

Study drug from the ex-U.S. sites were destroyed at each country's selected facility.

3.6 CONCOMITANT MEDICATIONS

Concomitant therapy included oral contraceptives, hormone-replacement therapy, or other maintenance therapy. All concomitant medications were reported to the investigator and recorded on the appropriate eCRF. Patients were encouraged to use the minimal dose required to control their symptoms.

All patients were allowed to take study-defined H1 antihistamine medications at approved doses during the screening, treatment, and follow-up periods, which is typical for placebo-controlled trials where an add-on therapy is studied for a disease with a pre-existing standard of care. Since the cellular mechanisms responsible for the efficacy of H1 antihistamines and omalizumab in CIU are not sufficiently understood, it was not possible to test whether omalizumab provides efficacy by potentiating H1 antihistamine

efficacy. Patients remained on a stable H1 antihistamine treatment regimen throughout the study period. Diphenhydramine (25 mg) was provided and used on an as-needed basis (up to a maximum of three doses in 24 hours or less, based on local regulations) during the screening, treatment, and follow-up periods. Therapies used for the treatment of CIU prior to enrollment were collected as part of the patient's medical history.

Prior to the screening visit (– 14 days) and during the study, the following medications and treatments were restricted:

- Routine (daily or every other day during 5 or more consecutive days) doses of the following medications within 30 days prior to Day – 14: systemic or cutaneous (topical) corticosteroids (prescription or over the counter), hydroxychloroquine, methotrexate, cyclosporine, or cyclophosphamide
- Routine (daily or every other day during 5 or more consecutive days) doses of doxepin within 14 days prior to Day – 14
- Omalizumab within 1 year prior to screening
- Any LTRAs (montelukast or zafirlukast) or H2 blockers within 7 days prior to Day – 14
- Any H1 antihistamines at greater than approved doses within 3 days prior to Day – 14
- Either IVIG or plasmapheresis within 30 days prior to Day – 14

Patients who received any excluded therapy during screening were considered a screening failure. Patients who received any excluded therapy after randomization were discontinued from study treatment; if a patient had received at least one dose of study drug following enrollment, the patient was followed for safety for the remainder of the study.

Patients taking either LTRAs or H2 blockers for diseases other than CIU (e.g., asthma or gastroesophageal reflux disease [GERD], respectively) were permitted to continue their use during the study. These diseases were recorded as part of the medical history collected during the screening period. Inhaled asthma controllers, including corticosteroids, were also permitted during the study.

3.7 ASSESSMENTS

The evaluations and procedures performed during the study are detailed in Appendix A-1 of the Study Q4881g protocol on page 1479. Assessments included medical history and concomitant medications, vital signs, physical examination, laboratory assessments, PK/PD assessment, ATA assessment, exploratory blood ribonucleic acid (RNA) and serum biomarker samples, in-clinic measured UAS, patient eDiary, and patient reported outcomes (PRO). For details on the scheduled assessments to determine trough serum levels of omalizumab (PK), serum free-IgE (PD), and total-IgE (PD) see Appendix A-2 of the Study Q4881g protocol on page 1483. For details on data processing methods see

the bioanalytical reports for serum total omalizumab levels on page 2664 total IgE determination on page 2480 free IgE levels on page 2582 and ATA on page 2513..

3.7.1 Definitions of Study Assessments

3.7.1.1 Urticaria Patient Daily Diary

The primary efficacy endpoint and many of the secondary and exploratory efficacy endpoints were collected via the Urticaria Patient Daily Diary (UPDD) with an electronic handheld device (eDiary). The UPDD is a patient diary developed on the basis of endpoints used in previously approved therapies for chronic urticaria (CU), has been previously validated for use in adults and adolescents with CIU, and has robust measurement properties, including content validity, responsiveness to change and test-retest reliability (Mathias et al. 2010, 2012; Flood et al. 2012). The UPDD questions consist of the UAS (e.g., itch severity, number of hives), largest hive size, sleep interference score, activity interference score, diphenhydramine (rescue medication) use, angioedema episodes and management, and health care provider contact for CIU (see Table 3 of this CSR and Appendix B of the protocol on page 1484). The eDiary was completed twice per day by the patient for the duration of the study. The eDiary was given to the patient at the Day −14 visit. Patient compliance with eDiary completion was high in both the treatment and follow-up periods and is described in Section 5.5.2.1.

Table 3 Urticaria Patient Daily Diary Components

UPDD Component	Daily Assessment Schedule	Score Ranges & Response Categories
Itch severity	Twice daily	0=none 1=mild 2=moderate 3=severe
Number of hives	Twice daily	0=none 1=between 1 and 6 hives 2=between 7 and 12 hives 3=greater than 12 hives
Size of largest hive	Twice daily	0=none 1=less than 1.25 cm 2=between 1.25 cm and 2.5 cm 3=greater than 2.5 cm
Sleep interference	Once daily	0=No interference 1=Mild, little interference with sleep 2=Moderate, awoke occasionally, some interference with sleep 3=Substantial, woke up often, severe interference with sleep
Daily Activity Interference	Once daily	0=No interference 1=Mild, little interference with daily activities 2=Moderate, some interference with daily activities 3=Substantial, severe interference with daily activities
Rescue medication use (tablets diphenhydramine 25 mg)	Once daily	Number of tablets recorded
Angioedema	Once daily	0=No 1=Yes
Angioedema management	Once daily	0=Did nothing 1=Took some prescription or non-prescription medication 2=Called my doctor, nurse or nurse practitioner 3=Went to see my doctor, nurse or nurse practitioner 4=Went to the emergency room at the hospital 5=Was hospitalized
Health care provider contact due to CIU	Once daily	0=No 1=Yes

CIU = chronic idiopathic urticaria; UPDD = Urticaria Patient Daily Diary.

Source: page 1484)

3.7.1.2 Patient Reported Outcomes

The Medical Outcomes study (MOS) Sleep Scale (see Appendix C of the protocol on page 1490), Dermatology Life Quality Index (DLQI) (see Appendix D of the protocol on page 1493), EuroQoL-5D (EQ-5D) (see Appendix E of the protocol on page 1495), and Chronic Urticaria Quality-of-Life Questionnaire (CU-Q2oL) were performed prior to study drug administration when applicable. It should be noted that the CU-Q2oL was not available in all regions because of a lack of certified translated documents for instruments.

Dermatology Life Quality Index

The DLQI is a 10-item dermatology-specific health-related quality-of-life measure (Finlay and Khan 1994). Patients rated their dermatology symptoms as well as the impact of their skin condition on various aspects of their lives. An overall score was calculated as well as the following domain scores: Symptoms and Feelings, Daily Activities, Leisure, Work and School, Personal Relationships, Treatment. The overall DLQI score has a range of 0–30; a lower score indicates a better quality-of-life and a higher score indicates lower quality-of-life. The minimally important difference (MID) of the overall DLQI score for patients with CIU has been estimated to be 2.24–3.10 (Shikiar et al. 2005).

Chronic Urticaria Quality-of-Life Questionnaire

The CU-Q2oL is a 23-item CIU-specific health-related quality-of-life questionnaire (Baiardini et al. 2005). Patients rated their CIU symptoms and the impact of their CIU on various aspects of their lives. An overall score was calculated as well as the following domain scores: Pruritus, Swelling, Impact on Life Activities, Sleep Problems, Limits, and Looks.

EuroQoL-5D Questionnaire

The EQ-5D questionnaire is a generic preference-based health-related quality-of-life questionnaire that provides a single index value for health status (EuroQol Group 1990). The EQ-5D questionnaire is designed for self-completion by patients and consists of five questions each with three possible categories (no problems, moderate problems, severe problems) and a visual analog scale from 0 (worst possible health state) to 100 (best possible health state). Patients were asked to rate their health-related quality-of-life during the past day. The five questions comprise five dimensions of health (Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression). A EuroQoL-5D Index Score was constructed using the five questions and the appropriate population-based weights. The data from the visual analog scale was summarized in the Health State variable.

Medical Outcomes Study Sleep Scale

The MOS Sleep Scale is a 12-item questionnaire asking patients to rate various dimensions of their sleep over the past four weeks (Hays and Stewart 1992, Spritzer and Hays 2003). Nine MOS Sleep sub-scales were derived: Sleep Disturbance,

Snoring, Short of Breath or Headache, Sleep Adequacy, Somnolence, Sleep Problems Index I, Sleep Problems Index II, Sleep Quantity, and Optimal Sleep.

For definitions of the other study assessments see Section 4.5.1 of the protocol on page 1444.

3.7.1.3 Screening and Pretreatment Assessments

Written informed consent for participation in the study was obtained before performing any study-specific screening tests or evaluations and before restricting medications and treatments. The informed consent process was documented in the patient's medical chart. ICFs for patients who were not subsequently enrolled were maintained at the study site.

Screening and pretreatment tests and evaluations were performed within 14 days preceding Day 1 (defined as the day of first dose of study drug), unless otherwise specified. Extensions to the screening period were permitted under exceptional circumstances if information concerning eligibility was outstanding. Results of standard-of-care examinations performed prior to obtaining informed consent and within 14 days prior to study entry were used in lieu of repeating examinations for screening.

Patients were instructed on the use and completion of their electronic diaries at screening and the diaries were reviewed by the study personnel on Day 1 to ensure that they were being completed correctly.

3.7.1.4 Assessments during Treatment

All screening evaluations were completed and reviewed to confirm that patients met all eligibility criteria before the first injection of study drug.

The Week 12 visit was scheduled on Day 85 (not on Day 84 or earlier). A +3-day window from the scheduled date was permitted.

All assessments were performed at the time of the specified visit unless a time window was specified. Assessments scheduled on the day of study drug administration were performed prior to study drug administration, unless otherwise noted.

3.7.1.5 Study Completion/Early Termination Visit

Patients who withdrew from study treatment were encouraged to continue attending the clinic every 4 weeks as per the Study Flowchart provided on page 1479 and on page 1483, and at minimum were asked to return to the clinic ≤16 weeks after the last dose administered for an early termination visit.

3.7.1.6 Follow-Up Assessments

Ongoing adverse events (AEs) suspected by the Investigator to be related to omalizumab were followed until the event had resolved to baseline grade; the event was

assessed by the investigator as stable; the patient was lost to follow up; the patient withdrew consent; or until it had been determined that the study treatment or participation was not the cause of the AE.

3.7.1.7 Unscheduled Visits

Patients came in to the clinic for unscheduled visits to assess AEs or SAEs that occurred during the study. These visits were recorded and no specific evaluation or diagnostic testing was required on these days. Concomitant medication usage was collected.

A sample eCRF is provided on page 1599.

3.7.2 Assay Methods

Serum total omalizumab levels, as well as total and free IgE levels, were measured in validated quantitative immunoassays. ATAs were detected using a pair of fragment ELISAs. Samples that screened positive for ATA were further characterized using an immunodepletion-based assay. For details on assay methods see the bioanalytical reports for serum total omalizumab levels on page 2664 total IgE determination on page 2480free IgE levels on page 2582 and ATA on page 2513.

3.8 DATA REPORTING AND ANALYSIS PLAN

The procedures described in the statistical analysis plan (SAP) provided on page 1658 supersede those in the protocol.

The SAP (see page 1659) was amended once on 4 December 2012 to include the analysis of complete response (UAS7 = 0) as an additional clinically important endpoint. The key changes were as follows:

- Addition of proportion of complete responders (UAS7 = 0) at Week 12 as a secondary endpoint
- Addition of proportion of complete responders (UAS7 = 0) at Week 24 and Week 40 as exploratory endpoints

Descriptive summaries of continuous data included the group mean, standard deviation (SD), median, minimum, maximum, and sample size. Descriptive summaries of discrete data reported the number of patients and incidence as a frequency and as a percentage.

This clinical study report (CSR) includes efficacy and safety analyses performed using data collected from study initiation (first patient enrolled on 16 February 2011) to database lock on 11 December 2012.

3.8.1 Statistical Hypothesis and Planned Sample Size

3.8.1.1 Hypothesis

The statistical analyses tested the null hypothesis of no difference between the placebo group and each omalizumab group.

3.8.1.2 Sample Size

The sample size for this study was primarily based on safety and regulatory considerations. The estimation of power for efficacy assumed a mean change from baseline in the weekly itch severity score at Week 12 to be 9 points and 3.5 points for the omalizumab and placebo groups, respectively, with a common SD of 6 points (based on data from Studies Q4577g and CIGE025ADE05). Assuming an early discontinuation rate of 15% (based on data from the same two studies) by Week 12, a total of 300 patients (1:1:1:1 randomization ratio with 75 patients in each treatment group) would yield approximately 98% power to detect a difference in treatment effect in the primary endpoint at the 0.05 level for any omalizumab group. A multiplicity type I error control plan was employed to adjust for the comparisons of multiple omalizumab groups to the placebo group in order to maintain an overall type I error rate of 0.05 (two sided).

3.8.2 Analysis Populations

Four analysis populations are defined for this study: randomized population, modified intention-to-treat (mITT) population, safety-evaluable population, and PK-evaluable population.

3.8.2.1 Randomized Population

The randomized population included all randomized patients regardless of whether they received any study drug. Treatment groups for this population were defined according to the treatment assigned at randomization by the IxRS.

3.8.2.2 Modified Intention-To-Treat Population

This population included all patients randomized in the study who received at least one dose of study drug. The treatment group for this population was defined according to the treatment assigned at randomization by the IxRS. This analysis population was used for efficacy analysis unless otherwise specified.

3.8.2.3 Pharmacokinetic-Evaluable Population

PK-evaluable patients included randomized patients who received at least one dose of study drug and had provided at least one serum sample for the determination of omalizumab concentration. The PK-evaluable population was analyzed according to treatment received.

3.8.2.4 Safety Population

This population included patients who received at least one dose of study drug. Treatment groups for this population were defined according to the actual treatment received during the treatment period as follows:

- Placebo: Patients who received only placebo injections (i.e., no active treatment) during the treatment period
- 75-mg omalizumab: Patients who received at least one 75-mg omalizumab injection but no higher active dose level (i.e., 150-mg or 300-mg) injections during the treatment period

- 150-mg omalizumab: Patients who received at least one 150-mg omalizumab injection but no higher active dose level (i.e., 300-mg) injections during the treatment period
- 300-mg omalizumab: Patients who received at least one 300-mg omalizumab injection during the treatment period

This analysis population was used for analysis of all safety endpoints.

If there are no differences between the IxRS assignment and actual treatment received during the treatment period, the mITT and the safety population will be the same population.

3.8.3 Efficacy Analysis

Unless otherwise specified, all analyses of efficacy outcomes from the treatment period were based on the mITT population. Patients were analyzed according to the treatment arm to which they were randomized. Treatment comparisons were performed between each of the omalizumab groups (75 mg, 150 mg, and 300 mg) and the placebo group. All statistical tests were two-sided using an overall 0.05 level of significance and adjustments for multiple comparisons were performed according to the type I error control plan using a hierarchical order detailed in Section 4.8 of the SAP on page 1691.

3.8.3.1 Primary Efficacy Endpoint

The primary efficacy endpoint was the change from baseline in the weekly itch severity score at Week 12; defined as the Week 12 weekly itch severity score minus the baseline weekly itch severity score. Changes from baseline in weekly itch severity score for other study weeks were calculated similarly. For details on the weekly itch severity score see Section 4.4.1 of the SAP on page 1673.

Every effort was made to continue to follow patients who discontinued from study treatment. Patients who discontinued prematurely from study treatment or who received excluded therapy during the treatment period were encouraged to remain in the study and enter the 16-week follow-up period. These patients were considered discontinued from study treatment as of the earlier of a) the protocol-specified visit day of the first missed treatment; or b) the date they started taking the excluded therapy. Subsequent daily diary scores were deemed missing for the purposes of the efficacy analyses. This principle was applied to other efficacy outcomes, which were in the form of weekly scores derived from the patient daily diary data.

Missing Week 12 weekly itch severity scores were imputed by carrying forward the baseline weekly itch severity score. For summaries by study week, the weekly itch severity scores are presented using baseline-carry-forward (BOCF) values. Similar summaries are presented using observed (not imputed) values.

The mean and SD of the change from baseline in weekly itch severity scores for each treatment group are presented by study week. The analysis of the change from baseline

in weekly itch severity score at Week 12 consisted of treatment comparisons between each of the omalizumab groups (75 mg, 150 mg, and 300 mg) and the placebo group using analysis of covariance (ANCOVA), controlling for baseline weekly itch severity score (<13 vs. ≥ 13), and baseline weight (<80 kg vs. ≥ 80 kg). A separate ANCOVA model was run for each omalizumab dose group versus placebo. The least squares means (LSM) and the corresponding 95% confidence intervals (CIs) of the differences between each of the omalizumab groups and the placebo group are presented along with the p-values for treatment differences resulting from the ANCOVA model.

3.8.3.2 Secondary Efficacy Endpoints

Table 4 provides an overview of the analyses methods for each secondary endpoint. For details on each secondary endpoint see Section 4.4.2 of the SAP on page 1675.

Table 4 Statistical Analyses of Secondary Endpoints

Secondary Endpoint (Presented in order of Hierarchical Testing)	Statistical Test	Baseline Covariates / Stratification Variables	Handling of Missing Data (Imputation Method) *
Change from baseline in UAS7 at Week 12	ANCOVA	UAS7 [a] and weight [b]	BOCF
Change from baseline in weekly number of hives score at Week 12	ANCOVA	Weekly number of hives score [a] and weight [b]	BOCF
Time to MID response in weekly itch severity score by Week 12	Cox PH	Weekly itch severity score [c] and weight [b]	Censored [d] in the absence of MID response
Proportion of patients with UAS7 $\leq$ 6 at Week 12	CMH	UAS7 and weight [b]	Classified as Non-responders [e]
Proportion of weekly itch severity score MID responders at Week 12	CMH	Weekly itch severity score and weight [b]	Classified as Non-responders [f]
Change from baseline in weekly size of largest hive score at Week 12	ANCOVA	Weekly size of largest hive score [a] and weight [b]	BOCF
Change from baseline in DLQI at Week 12	ANCOVA	DLQI [a] and weight [b]	No imputation
Proportion of angioedema-free days from Week 4 to Week 12 of therapy	Van Elteren's test [g]	Presence of angioedema at baseline [h] and weight [b]	No imputation
Proportion of Complete Responders (UAS7 = 0) at Week 12	CMH	UAS7 [a] and weight [b]	Classified as Non-responders

ANCOVA = analysis of covariance; BOCF = baseline-carry-forward; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; MID = minimally important difference; PH = Proportional Hazards; UAS7 = urticaria activity score over seven days

[*] See SAP for details.

[a] Baseline variable stratified as < median vs. $\geq$ median.

[b] Baseline weight stratified as < 80 kg vs. $\geq$ 80 kg.

[c] Baseline variable stratified as < 13 vs. $\geq$ 13.

[d] Censored at the date of the last non-missing weekly itch severity score.

[e] Patients with missing UAS7 at Week 12 were imputed as nonresponders (UAS7 $\geq$ 7)

[f] Patients with missing weekly itch severity score at Week 12 were imputed as nonresponders (patient did not reach MID).

[g] Van Elteren's test: stratified Wilcoxon rank sum test.

[h] Variable stratified as yes vs. no.

The multiplicity plan applied to the secondary endpoints provides strong control of the type I error rate at 0.05 within each dose by the prespecified hierarchical order of the secondary endpoint tests as outlined in Section 4.8.2 of the SAP on page 1691.

3.8.3.3 Additional Analyses of the Primary Endpoint

Sensitivity analyses of the primary endpoint were performed to compare each omalizumab dose group to placebo:

- An ANCOVA model was fitted which is similar to the primary analysis but imputes missing Week 12 weekly itch severity scores by the method of last observation carry forward (LOCF). That is, for patients who had a missing Week 12 weekly itch severity score, the Week 12 weekly itch severity score was imputed by the last non-missing weekly itch severity score. As in the primary analysis, the ANCOVA model controlled for baseline weekly itch severity score (< 13 vs. ≥ 13) and baseline weight (< 80 kg vs. ≥ 80 kg), and a separate ANCOVA model was run for each omalizumab dose group versus placebo.
- A mixed effects model was fitted which included all observed weekly itch severity scores from baseline to Week 12. No imputation was applied to those weeks with a missing weekly itch severity score. The baseline weekly itch severity score (< 13 vs. ≥ 13), baseline weight (< 80 kg vs. ≥ 80 kg), treatment group (omalizumab versus placebo), and time were included as covariates in the model. A separate model was run for each omalizumab dose group versus placebo.
- An ANCOVA model was fitted, which was similar to the primary analysis but imputed the Week 12 weekly itch severity score by carrying forward the baseline weekly itch severity score (BOCF) for patients who received any systemic steroids for any reason during the 2 weeks prior to the Week 12 visit (Days 71 to 84). As in the primary analysis, the ANCOVA model controlled for baseline weekly itch severity score (< 13 vs. ≥ 13) and baseline weight (< 80 kg vs. ≥ 80 kg), and a separate ANCOVA model was run for each omalizumab dose group versus placebo.

3.8.3.4 Exploratory Efficacy Analysis

Table 5 provides an overview of the analyses methods for each exploratory endpoint. For details on each exploratory endpoint see Section 4.4.3 of the SAP on page 1680.

Table 5 Statistical Analyses of Exploratory Endpoints

Exploratory Endpoint	Statistical Test	Baseline Covariates/ Stratification Variables	Handling of Missing Data (Imputation Method) *
Change from Baseline Endpoints			
Weekly itch severity score at Week 24	ANCOVA	Weekly itch severity score [a] and weight [b]	BOCF
UAS7 at Week 24	ANCOVA	UAS7 [c] and weight [b]	BOCF
Weekly number of hives score at Week 24	ANCOVA	Weekly number of hives score [c] and weight [b]	BOCF
Weekly size of largest hive score at Week 24	ANCOVA	Weekly size of largest hive score [c] and weight [b]	BOCF
CU-Q2oL Overall Score at Week 12 and Week 40	ANCOVA	CU-Q2oL overall score [c] and weight [b]	No imputation
Overall DLQI at Week 40	ANCOVA	Overall DLQI [c] and weight [b]	No imputation
Proportion of itch-free days and/or hive-free days at Week 12 and Week 24	ANCOVA	Proportion of itch-free days and/or hive-free days [c] and weight [b]	BOCF
Number of tablets/week of sedating H1 antihistamine (diphenhydramine) for itch relief from baseline to Week 12	ANCOVA	Number of tablets/week of sedating H1 antihistamine [c] and weight [b]	BOCF
Weekly sleep interference score at Week 12 and Week 24	ANCOVA	Weekly sleep interference score [c] and weight [b]	BOCF
Weekly interference with daily activities score at Week 12 and Week 24	ANCOVA	Weekly interference with daily activities score [c] and weight [b]	BOCF
Health utility as measured by EQ-5D at Week 12 and Week 40	ANCOVA	EQ-5D [c] and weight [b]	No imputation
MOS Sleep Sub-scale Scores at Week 12 and Week 24	ANCOVA	MOS sleep sub-scale score [c] and weight [b]	No imputation
Endpoints that Consist of Proportion of Responders			
Proportion of patients with UAS7 $\leq$ 6 at Week 24	CMH	UAS7 [c] and weight [b]	Classified as Non-responders [d]
Proportion of Week 24 responders who maintain their response (UAS7 $\leq$ 6) to the Week 40 visit	Descriptive summary		Classified as Non-responders [e]
Proportion of patients with UAS7 $\leq$ 6 at Week 40	CMH	UAS7 [c] and weight [b]	Classified as Non-responders [f]

Table 5 Statistical Analyses of Exploratory Endpoints (cont.)

Exploratory Endpoint	Test	Stratification Variable	Handling of Missing Data (Imputation Method) *
Endpoints that Consist of Proportion of Responders (cont.)			
Proportion of Complete Responders (UAS7 = 0) at Week 24 and Week 40	CMH	UAS7 [c] and weight [b]	Classified as Non-responders [g]
Endpoints that Consist of Time to First Event (Response/Relapse)			
Time to UAS7 MID response by Week 12	Cox PH	UAS7 [c] and weight [b]	Censored [d] in the absence of MID response
Time to relapse in Week 24 responders		Descriptive summary	Censored [h,i] after the Week 24 visit
Other Endpoints			
Healthcare utilization [j]		Descriptive summary	
Action(s) taken in response to angioedema		Descriptive summary	
Correlation between basophil high-affinity IgE receptor density and change from baseline in weekly itch severity score at Week 12, Week 24, and Week 40		Descriptive summary	

ANCOVA = analysis of covariance; BOCF = baseline-carry-forward; CMH = Cochran-Mantel-Haenszel; CU-Q2oL = Chronic Urticaria Quality-of-Life Questionnaire; DLQI = Dermatology Life Quality Index; EQ-5D = EuroQoL-5D; MID = minimally important difference; MOS = Medical Outcomes Study; UAS7 = urticaria activity score over 7 days; PH = Proportional Hazards

* See SAP for details.

[a] Baseline variable stratified as < 13 vs. ≥ 13.

[b] Baseline weight stratified as < 80 kg vs. ≥ 80 kg.

[c] Baseline variable stratified as < median vs. ≥ median.

[d] Patients will be classified as nonresponders at Week 24 (i.e., did not achieve UAS7 < 6 at Week 24) if they had a missing UAS7 at Week 24.

[e] Patients with a missing UAS7 for any week from Week 25 to Week 40 were classified as not maintaining the response to the Week 40 visit.

[f] Patients will be classified as nonresponders at Week 40 (i.e., did not achieve UAS7 < 6 at Week 40) if they had a missing UAS7 at Week 40.

[g] Patients will be classified as non-responders at Week 24 or Week 40 (i.e., did not achieve UAS7=0 at Week 24 or Week 40) if they have a missing UAS7 at Week 24 or Week 40.

[h] Censored at the date of the last non-missing UAS7 evaluation.

[i] For any patient who maintains a UAS7 ≤ 6.

[j] Calling a doctor, nurse, or nurse practitioner) based on patient daily diary data.

3.8.3.5 Subgroup Analyses

Subgroup analyses were performed for the following demographic and baseline variables to evaluate consistency of the primary efficacy results. Subgroup analyses are considered to be supportive.

- Gender (Male, Female)
- Age (< 18, 18–64, ≥ 65 years)
- Race/ethnicity (White, Black or African-American, or Other)
- Region (within or outside the United States)
- Baseline weekly itch severity score (< 13, ≥ 13)
- Baseline UAS7 (< median, ≥ median)
- Body weight (< 80 kg, ≥ 80 kg)
- CU index test (Positive, Negative)
- Presence of angioedema at baseline (Yes, No)
- Previous use of systemic steroids for CIU (Yes, No)
- Level of thyroperoxidase antibody at baseline (High, Normal)
- Duration of disease prior to baseline (< 2, 2–10, > 10 years)
- Previous number of CIU medications (≤ 2, 3–5, > 5)

The mean and SD of the change from baseline in weekly itch severity scores at Week 12 by treatment group is presented for each subgroup level. In addition, the ANCOVA model specified in Section 4.4.1 of the SAP on page 1673 was applied separately to each subgroup level.

3.8.4 Pharmacodynamic and Pharmacokinetic Data Analysis

Total omalizumab levels were summarized using descriptive statistics. Free IgE and total IgE were summarized using mean and standard deviations by treatment group for the visit at which they were measured. The summaries include the raw data as well as change from baseline. The PK-evaluable population was analyzed according to treatment received.

3.8.5 Safety Reporting and Analysis

Safety was assessed through the summary of AEs, laboratory test results, vital signs, and antibodies to omalizumab. Separate summaries were produced for the whole study, the 24-week treatment period, and the 16-week follow-up period. Safety analyses included the safety-evaluable patients. Patients were analyzed according to the actual treatment received.

3.8.5.1 Exposure of Study Drug

The number of doses and the total dose (mg) of study drug administered during the study was summarized by treatment group. The duration of study drug exposure was

also summarized by treatment group. The duration of study drug exposure was defined as the date of the last treatment visit minus the date of the first study drug administration + 1 day + 28 days. If a patient received study drug after their last scheduled treatment visit as an error, the date of the last dose of study drug was taken as the treatment end date.

3.8.5.2 Adverse Events

Verbatim descriptions of AEs were coded and analyzed using the current version (at the time of database lock) of the Medical Dictionary for Regulatory Activities (MedDRA Version 15.1) terminology for AEs. A glossary of AEs is provided on page 1796.
A treatment-emergent AE is defined as any AE reported on or after the first dose of study drug. Treatment-emergent AEs were summarized by treatment group for each of the following:

- All AEs
- All AEs by severity (mild, moderate, severe)
- SAEs
- AEs leading to discontinuation of study drug
- Deaths

Narratives are provided for all patients who experienced SAEs, AEs that led to withdrawal from study treatment or from the study, pregnancies, and all possible cases of anaphylaxis under the heading AEs of special interest (AESIs).

On the basis of known/suspected drug administration effects, the AEs listed below are of special interest with omalizumab treatment. Identification of patients with treatment-emergent AEs of special interest (AESIs) was achieved by an ascertainment process based on a search of MedDRA preferred terms, SMQ searches, or modified SMQ searches. Possible events were identified using the search criteria described below. Because these search criteria were broad, for anaphylaxis and serum sickness syndrome the Sponsor clinical and safety scientists reviewed each case identified by the MedDRA search to determine whether the case qualified for the specified event of special interest. In addition to reviewing all events identified by MedDRA searches, detailed narratives for all SAEs were manually reviewed by the Sponsor clinical and safety scientists in order to capture any other suspected cases of anaphylaxis. All clinical and safety scientist reviews of AESIs were conducted by unblinded personnel, with the exception of the blinded external Anaphylaxis Review Committee.

- Anaphylaxis

  Patients with possible anaphylaxis or its components (Sampson et al. 2006) were identified in three different ways using the anaphylactic reaction Standard MedDRA Query (SMQ). In the first method, a narrow search containing any preferred terms that represented core anaphylactic reaction terms (Category A) was used to identify cases. In the second method, a broad SMQ search contained additional terms

(added to those included in the narrow search) that were signs and symptoms possibly indicative of anaphylactic reaction (Category B, C, D, or E). The third method used was an algorithmic search which required a patient to have a narrow term (Category A) or at least one of the following combinations of these signs and symptoms: Category (B and C) or (D and [B or C]) or (E and [B or C or D]).

The categories were defined as follows:

A. Core anaphylactic reaction terms (e.g., anaphylactic reaction, anaphylactic shock, anaphylactoid shock, circulatory collapse, first use syndrome, shock, Type I hypersensitivity)

B. Upper airway/respiratory terms (e.g., acute respiratory failure, asthma, dyspnea, labored respiration)

C. Angioedema/urticaria/pruritus/flush terms (e.g., allergic edema, angioedema, erythema, urticaria acute)

D. Cardiovascular/hypotension terms (e.g., blood pressure decreased, cardiac arrest, hypotension)

E. Gastrointestinal terms (e.g. retching, vomiting, vomiting projectile, abdominal pain, abdominal pain upper, abdominal pain lower, abdominal rigidity, abdominal tenderness, gastrointestinal pain, esophageal pain)

The Anaphylactic Reaction SMQ (MedDRA Version 15.1) defines Categories A, B, C, and D. A fifth category (Category E) for gastrointestinal symptoms has been added by the Sponsor, consistent with international guidelines (Sampson et al. 2006). The preferred term lists for each category are found in Appendix 1 of the Charter for the Anaphylaxis Review Committee (reported separately).

Patients with possible anaphylactic reactions identified through use of Methods 2 and 3 (broad search terms beyond core terms) were clinically evaluated using the Sampson criteria (Sampson et al. 2006). In addition, the events were further evaluated by Sponsor clinical and safety scientists using the following temporal criteria: the ascertainment algorithms required that events in multiple categories (B, C, D, and E) had to have an onset within 24 hours of each other and have occurred $\leq$72 hours of study drug administration. These temporal criteria were intentionally designed to encompass a substantially wider timeframe than those specified in international guidelines (Sampson et al. 2006) in order to capture all possible cases of anaphylaxis.

All possible cases identified using Methods 1–3 which were not eliminated during Sponsor clinical and safety scientist adjudication were then blinded and submitted as suspected cases to the external Anaphylaxis Review Committee for final confirmation of anaphylaxis events. In addition, any other suspected cases of anaphylaxis identified by the Sponsor clinical and safety scientists through the manual review of SAE narratives were also submitted as blinded cases to the external Anaphylaxis Review Committee for final confirmation of anaphylaxis events. Methods for the blinded, external adjudication of events are found in the Charter for the Anaphylaxis Review Committee (reported separately).

- Churg-Strauss syndrome

  Patients with potential Churg Strauss syndrome AEs were identified by two mechanisms: First, via a search for the core AE preferred term allergic granulomatous angiitis. Second, Sponsor clinicians evaluated cases identified by a wider search for high-level group term vascular inflammations and the high-level terms eosinophilic disorders and vasculitides not elsewhere classifiable (NEC).

- Hypersensitivity (does not include anaphylaxis, injection-site reaction, urticaria, skin rash)

  Patients with potential hypersensitivity reactions were identified by the high-level term angioedemas and the preferred terms allergic cough, allergic oedema, allergic pharyngitis, allergic respiratory symptom, application site hypersensitivity, asthma, blepharitis allergic, bronchospasm, dermatitis allergic, erythema multiforme, erythema nodosum, eye allergy, eye pruritus, eye swelling, hypersensitivity, immediate post-injection reaction, infusion site hypersensitivity, laryngitis allergic, pruritus allergic, skin reaction, Stevens-Johnson syndrome, Type I hypersensitivity, Type II hypersensitivity, Type III immune complex mediated reaction, Type IV hypersensitivity reaction, drug eruption, drug hypersensitivity, drug rash with eosinophilia and systemic symptoms, reaction to drug excipients, toxic epidermal necrolysis, toxic skin eruption, epiglottic oedema, laryngeal obstruction, laryngeal oedema, laryngospasm, laryngotracheal oedema, stridor, allergic respiratory symptom, and chest discomfort.

- Injection-site reactions

  Patients were identified using a search for injection site reactions (SMQ extravasation events [injection, infusion, and implants] search).

- Malignancy

  Patients were identified using a search for malignancies (SMQ malignancies search, including all four sub-SMQs malignancy related conditions, malignancy related therapeutic and diagnostic procedures, malignant or unspecified tumours, and tumour markers).

- Serum sickness syndrome

  Patients with potential events were identified in two ways. First, via a narrow search for patients with either an AE with a preferred term of serum sickness; and second, a broader search for patients with at least one AE from Category A (skin-related) and at least one event from Category B (generalized). AEs in Category A were defined by the high-level group term epidermal and dermal conditions and the high-level term urticarias. AEs in Category B were defined by the preferred terms influenza, arthralgia, pyrexia, and influenza like illness, and the high-level term skin vasculitides. Identified potential cases were evaluated by Sponsor clinical and safety scientists as possible components of serum sickness using the following criteria: the symptoms from Category A and Category B were required to occur within 7 days of each other, and the Category A event was not urticaria.

- Skin rash

  Patients were identified by the high-level terms erythemas, pruritus NEC, rashes, eruptions, and exanthems NEC.

- Thrombocytopenia and bleeding-related disorders

  Patients were identified using a search for thrombocytopenia (SMQ thrombocytopenia search, subgroup of SMQ hematopoietic cytopenias), or a search for hemorrhages (SMQ hemorrhages search).

- Hematopoietic cytopenias

  Patients were identified using a search for hematopoietic cytopenias (SMQ hematopoietic cytopenias search).

- Arterial thrombotic events (ATE)

  Patients were identified using the AE search strategy below.

  Cardiovascular death: Patients with cardiovascular death were identified by the preferred term cardiac death, sudden death, sudden cardiac death.

  Myocardial infarction: Patients were identified using a search for myocardial infarction (sub-SMQ myocardial infarction search, Level 2 under SMQ ischaemic heart disease, 20000047).

  Unstable angina: Patients were identified using a search for other ischaemic heart disease (SMQ other ischaemic heart disease search, Level 2, 20000168).

  Stroke: Patients were identified using a search for ischaemic cerebrovascular conditions (sub-SMQ ischaemic cerebrovascular conditions search, Level 3 under Cerebrovascular disorders, 20000063), haemorrhagic cerebrovascular conditions (sub-SMQ haemorrhagic cerebrovascular conditions search, Level 3 under Cerebrovascular disorders, 20000064), and the preferred terms hemiparesis, amaurosis fugax, hemiplegia.

  Transient ischaemic attack: Patients were identified by the high-level terms for transient cerebrovascular events.

  Note that myocardial infarction and unstable angina are sub-SMQs under SMQ of ischemic heart disease.

- Asthma/bronchospasm

  Patients were identified using a search for asthma/bronchospasm (SMQ asthma/bronchospasm search).

- Liver-related investigations, signs and symptoms

  Patients were identified using a search for AEs of liver-related investigations, signs and symptoms (SMQ Liver-related investigations (lab values and procedures), signs and symptoms search). No protocol-derived liver enzyme or bilirubin testing was performed post baseline, but AEs based on local laboratory values are all included in the safety database.

For further details on safety parameters and definitions, and timing for capturing and assessing safety parameters see Section 5.1 and Section 5.2 of the protocol on page 1458 and page 1460, respectively.

3.8.5.3 Laboratory Data

Descriptive summaries of baseline serum chemistry and urinalysis values were generated by treatment group. Hematology values were summarized at baseline and throughout the study by treatment group. Changes from baseline in clinical laboratory values and the proportion of patients experiencing changes relative to baseline based on central lab ranges for the specific tests are presented by treatment group. Central Laboratory Reference ranges (see page 1745) were used for the analysis of laboratory test parameter values.

The baseline value of any variable was defined as the last available value prior to the first administration of study drug for the treatment period (Day 1), unless otherwise specified.

3.8.5.4 Vital Signs

A patient listing of vital signs was generated. Vital signs include pulse and systolic and diastolic blood pressure (DBP).

3.8.5.5 Anti-therapeutic Antibodies

ATA data were reported for each treatment group at the end of the follow-up visit (Week 40), along with an estimate of the proportion of patients with treatment-emergent positive ATAs at Week 40.

3.8.6 Changes in Conduct of Study or Planned Analyses

3.8.6.1 Protocol Amendments

The study protocol (see page 1398) was amended once on 11 January 2011.

The purpose of the amendment was to modify the study design according to recommendations by the U.S. FDA, internal Genentech staff, and external experts. The key changes to the protocol were as follows:

- The number of weeks that a patient must have had CIU symptoms despite being on H1 antihistamines was increased from 6 to 8 weeks.
- The secondary objectives were clarified to indicate that a goal of this study was to provide information regarding the recurrence of disease/symptoms after withdrawal of omalizumab in patients with refractory CIU. Secondary and exploratory endpoints were modified as a result.
- Procedures regarding the use of excluded therapy were modified in an effort to continue to follow patients for safety evaluation after they had discontinued study drug treatment.
- The washout period required after regular doxepin use prior to enrollment was reduced from 6 weeks to 14 days.

- The criterion for women of childbearing potential and pregnancy was clarified. Additionally, nursing women were excluded from study participation.
- Contraindications to diphenydramine were added.
- The in-clinic UAS terminology was corrected.
- The start of the screening period was modified from 14−18 to 12−18 days prior to Day 1.
- The difference between discontinuation from study treatment and discontinuation from the study was clarified.
- The Medical Monitor was replaced.

3.8.6.2 Changes to Planned Analyses

The procedures described in the SAP provided on page 1658 supersede those in the protocol. The amendments made to the SAP are described in Section 3.8.

There were no changes to the planned analyses for the primary and secondary endpoints after the database lock.

4. RESULTS: STUDY POPULATION

4.1 DISPOSITION OF PATIENTS

The first patient was randomized on 16 February 2011, and the last patient completed the study on 17 October 2012. A total of 483 patients were screened in this study, and 319 patients were randomized in the study: 80 patients in the placebo group, 78 patients in the omalizumab 75-mg group, 80 patients in the omalizumab 150-mg group, and 81 patients in the omalizumab 300-mg group. The most frequent reasons for screening failures were patient unwilling to give written informed consent, adhere to the visit schedules and meet study requirements (14.0%), patient not diagnosed as having CIU refractory to H1 antihistamines at the time of randomization (10.5%), and other, not defined (27.5%). The number of screen failures and reasons for failure was collected on the IxRS database, which is not a validated source.

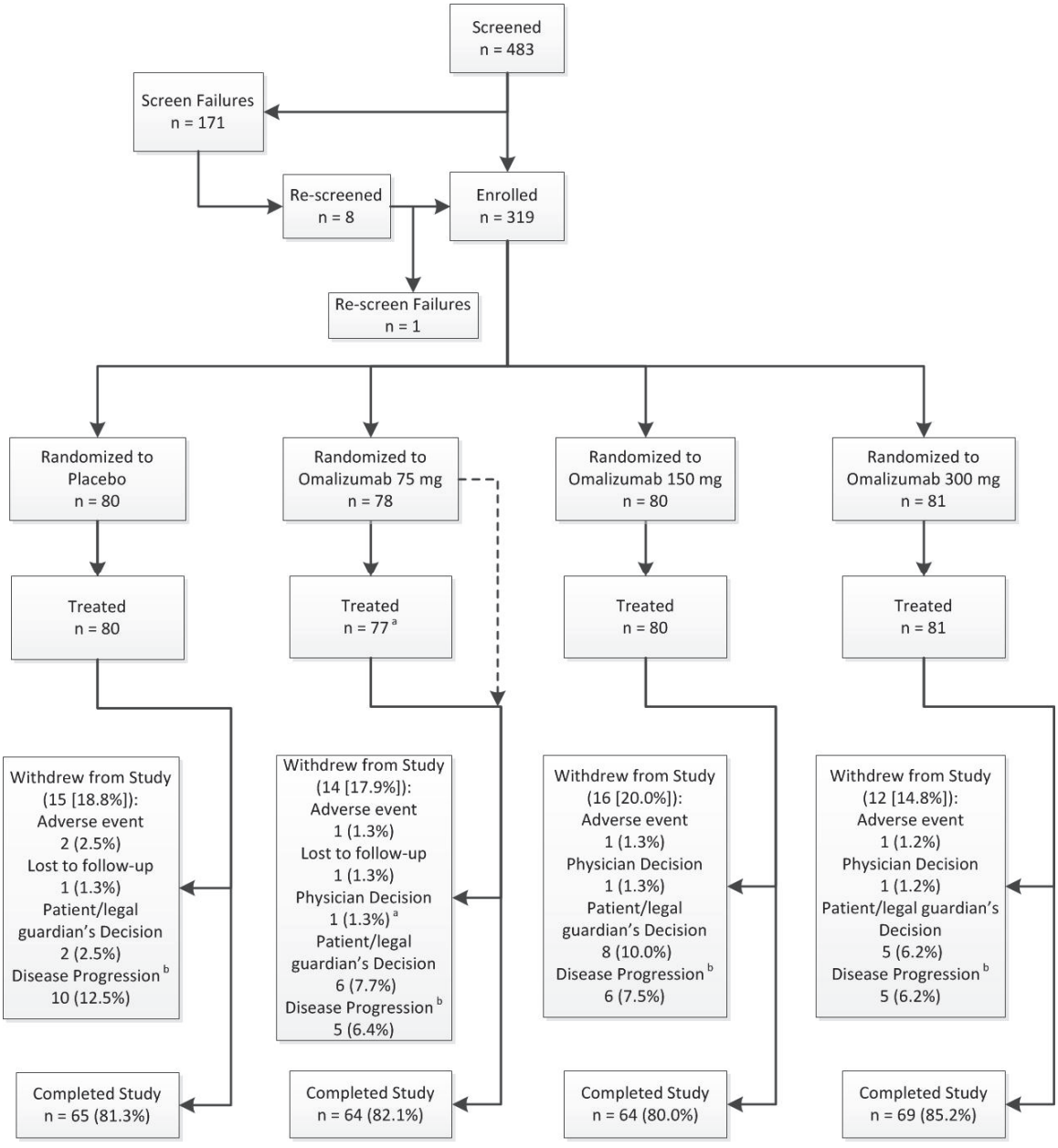
Patients were enrolled and randomized into the study at 53 centers in the following countries: United States (35 sites), Germany (5), Poland (4), France (3), Spain (2), Denmark (2), Italy (1), and Turkey (1). The United States enrolled the majority of patients (220 patients, 69.0%). The three highest-enrolling investigators were Investigator [redacted] in Poland (28 patients, 8.8%), Investigator [redacted] in the United States (20 patients, 6.3%), and Investigator [redacted] in Germany (16 patients, 5%). Enrollment by country and investigator is summarized on page 228.

Among the 319 patients randomized, 265 patients (83.1%) completed the study treatment, and 262 patients (82.1%) completed the study (see page 230). Overall, 57 patients (17.9%) discontinued prematurely from the study. The reasons for discontinuation from the study are summarized in Figure 2. The omalizumab 300-mg

group had the lowest study discontinuation rate (14.8%), followed by the omalizumab 75-mg (17.9%), placebo (18.8%), and omalizumab 150-mg (20.0%).

The most common reasons for study discontinuation for all four groups were subject or legal guardian's decision and disease progression. Disease progression was defined as either the worsening of or no improvement of the patient's disease. Patient retention is presented schematically on page 231.

Figure 2 Flow Diagram



Note: Percentages are based on the number of randomized patients.

[a] Patient [redacted] (randomized to omalizumab 75 mg) did not receive study drug as a result of not meeting all study eligibility criteria and was therefore not included in the mITT population

[b] Defined as either the worsening of or no improvement of the patient's disease

Source: page 230.

Patients who discontinued early from the study and the primary reason for discontinuation are listed on page 871 .

4.2 PATIENTS WITHDRAWN PREMATURELY FROM TREATMENT

Among the 319 randomized patients, 54 (16.9%) were discontinued from study drug treatment and one of these patients never received assigned study drug treatment (see Table 6). The omalizumab 300-mg group had the lowest study drug treatment discontinuation rate (9.9%). The most common reasons for study drug treatment discontinuation for all four groups were disease progression, patient or legal guardian's decision, and AE.

The placebo group had larger percentages of patients discontinuing treatment due to disease progression (12.5%) and AE (8.8%) than any of the other treatment groups. The reasons for discontinuation are summarized in Table 6. Of the 54 patients who withdrew prematurely from study drug treatment, 18 patients (6 in the placebo group, 4 in the 75-mg group, 7 in the 150-mg group, and 1 in the 300-mg group) remained on study and completed the 16-week follow-up period (see page 230 and page 871).

Table 6 Study Drug Treatment Withdrawn

Reason for Withdrawal	Placebo (n=80)	Omalizumab 75 mg (n=78)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Total	19 (23.8%)	11 (14.1%)	16 (20.0%)	8 (9.9%)	54 (16.9%)
Adverse event	7 (8.8%)	2 (2.6%)	4 (5.0%)	2 (2.5%)	15 (4.7%)
Lost to follow-up	1 (1.3%)	0	0	0	1 (0.3%)
Physician decision to discontinue treatment	0	3 (3.8%)	2 (2.5%)	1 (1.2%)	6 (1.9%)
Patient/legal guardian decision to discontinue treatment	1 (1.3%)	3 (3.8%)	5 (6.3%)	3 (3.7%)	12 (3.8%)
Disease progression [a]	10 (12.5%)	3 (3.8%)	5 (6.3%)	2 (2.5%)	20 (6.3%)

[a] Defined as either the worsening of or no improvement of the patient's disease

Source: page 230.

4.3 OVERVIEW OF ANALYSIS POPULATIONS

The analysis populations are summarized in Table 7. For definitions of each of the analysis populations, see Section 4.1 of the SAP on page 1670. The mITT population was the primary analysis population used for baseline characteristics summaries and efficacy analyses. For the safety population and the PK-evaluable populations, the treatment groups were defined on the basis of treatment actually received. These were the analysis populations used for the safety analyses and PK analyses, respectively.

One patient (Patient [redacted]) who did not meet all study eligibility criteria was randomized (omalizumab 75-mg group) and did not receive study drug; therefore, this patient was not included in the mITT population (see page 874). Seven patients (Patients [redacted], and [redacted]) randomized to the omalizumab 75-mg

group, received at least one dose of omalizumab 150-mg during the treatment period and were included in the omalizumab 150-mg group for the safety and PK analyses (see page 874 and page 952).

Table 7 Analysis Populations

Analysis Population	Placebo	Omalizumab 75 mg	Omalizumab 150 mg	Omalizumab 300 mg	All Patients
Randomized [a]	80	78	80	81	319
Modified intention-to-treat [b]	80	77 [c]	80	81	318
Pharmacokinetic evaluable [d]	80	70 [e]	87 [e]	81	318
Safety evaluable [f]	80	70 [e]	87 [e]	81	318

IxRS = Interactive Voice and Web Response System; mITT = modified intention to treat.

[a] Randomized: All randomized patients regardless of whether they received any study drug. Treatment groups were defined according to the treatment assigned at randomization by the IxRS.

[b] Modified intention-to-treat: All patients randomized in the study who received at least one dose of study drug. Treatment groups were defined according to the treatment assigned at randomization by the IxRS.

[c] Patient [redacted] who did not meet all study eligibility criteria was randomized and did not receive study drug, therefore was not included in the mITT population.

[d] Pharmacokinetic evaluable: Randomized patients who received at least one dose of study drug and provided at least one serum sample for determination of omalizumab concentration. Treatment groups for this population were defined according to the actual treatment received during the treatment period.

[e] Seven patients (Patients [redacted] and [redacted] randomized to the omalizumab 75-mg group, received at least one dose of omalizumab 150-mg during the treatment period and were included in the omalizumab 150-mg group for the safety and PK analyses.

[f] Safety evaluable: Patients randomized in the study who received at least one dose of study drug. Treatment groups for this population were defined according to the actual treatment received during the treatment period.

Source: page 232.

4.4 PROTOCOL VIOLATIONS

A total of 21 patients (6.6%) violated at least one eligibility criterion: 7 patients (9.0%) in the omalizumab 75-mg group, 5 patients (6.3%) in the omalizumab 150-mg group, 7 patients (8.6%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group (see page 233 and page 234). The most common eligibility criterion violated was the inclusion criterion of “Diagnosis of CIU refractory to H1 antihistamines at the time of randomization”, which occurred in 5 patients in the 75-mg group, 5 patients in the 150-mg group, 4 patients in the 300-mg group, and 1 patient in the placebo group.

Treatment errors occurred in eleven patients. Seven patients randomized to the 75-mg group received one dose of 150-mg omalizumab. Two patients (Patients [redacted] and [redacted] who were randomized to the 300-mg group, received one dose of 150-mg

omalizumab during the treatment period (see page 952). One patient (Patient [redacted] randomized to the 150-mg group received one dose of placebo, and one patient (Patient [redacted] randomized to the 75-mg group received one dose lower than 75-mg during the treatment period (see page 874 and page 952).

Eight patients received open-label omalizumab during the follow-up period (1 patient in the omalizumab 75-mg group, 2 patients in the omalizumab 150-mg group, 1 patient in the omalizumab 300-mg group, and 2 patients in the placebo group) (see page 874). The efficacy data collected on or after the date they received open-label omalizumab during the follow-up period were not used in any analyses and were considered missing. All safety events that occurred after a patient received open-label omalizumab during the follow-up period were listed separately (see page 1009). Once the Sponsor became aware of this protocol violation, the following actions were taken to prevent further open-label use of omalizumab: all sites were re-educated through "all site teleconferences," written memoranda were sent to all affected sites, and the sites were instructed to document the open-label use of omalizumab as a protocol violation.

Major protocol violations are summarized on page 238 and are defined as follows:

- Increases the risk or decreases the benefits of the study;
- Affects the validity of the data or information resulting from the completion of the approved protocol;
- Affects the scientific soundness of the investigational plan or protocol; and/or
- Affects the patient's rights, safety or welfare. A major protocol violation extends both to violations of informed consent and eligibility criteria, as well as violations that occur during the course of the study.

A total of 73 patients (22.9%) had a major protocol violation. The most common violations were use of a prohibited concomitant medication (55 patients; 17.2%) and failure to meet all study eligibility entry criteria (18 patients; 5.6%).

One patient (Patient [redacted]) who did not meet all study eligibility criteria was randomized in error, did not receive study drug and was, therefore excluded from mITT, safety and PK populations. Efficacy data excluded from analyses as a result of patients receiving open-label omalizumab were imputed according to the missing data handling rule specified in the SAP (see Section 4.7).

None of the violations were considered to have an effect on the integrity of the results. A listing of patients with protocol violations is provided on page 874.

4.5 DEMOGRAPHIC DATA AND BASELINE CHARACTERISTICS

Baseline demographics of the mITT population are summarized in Table 8. In general, the four treatment groups were balanced with respect to baseline demographics. Some differences were noted and include the following:

- The placebo group had a higher percentage of male patients (35%) than the other treatment groups (28.6%, 20.0% and 25.9% of patients in the 75-mg, 150-mg and 300-mg groups, respectively).
- The 300-mg omalizumab group had a higher percentage of white patients (91.4%) than the other 3 groups (80.0%, 80.5% and 78.8% of patients in the placebo, 75-mg and 150-mg groups, respectively).

The average age of patients in the study was 41.2 years (range, 12–74 years).
The majority of the patients were white (82.7 %) and female (72.6%). The mean weight was 82.2 kg and the mean body mass index (BMI) was 29.3 kg/m^2. The proportion of patients with a weight of $<$80 kg was 49.7%.

Table 8 Demographic and Baseline Characteristics: Modified Intent-to-Treat Population

Genentech, Inc. Study q4881g
Xolair (Omalizumab) Xolair in Refractory Chronic Idiopathic Urticaria (CIU)

Table 14.1/6
Demographic and Baseline Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Age (yr)					
n	80	77	80	81	318
Mean (SD)	40.4 (15.6)	40.7 (15.2)	41.1 (14.0)	42.4 (13.2)	41.2 (14.5)
Median	37.5	41.0	43.0	42.0	41.0
Range	13 - 74	13 - 72	12 - 68	14 - 72	12 - 74
Age group (yr)					
n	80	77	80	81	318
12-17	4 (5.0%)	5 (6.5%)	7 (8.8%)	2 (2.5%)	18 (5.7%)
18-40	41 (51.3%)	33 (42.9%)	29 (36.3%)	34 (42.0%)	137 (43.1%)
41-64	30 (37.5%)	35 (45.5%)	41 (51.3%)	42 (51.9%)	148 (46.5%)
>=65	5 (6.3%)	4 (5.2%)	3 (3.8%)	3 (3.7%)	15 (4.7%)
Sex					
n	80	77	80	81	318
Male	28 (35.0%)	22 (28.6%)	16 (20.0%)	21 (25.9%)	87 (27.4%)
Female	52 (65.0%)	55 (71.4%)	64 (80.0%)	60 (74.1%)	231 (72.6%)
Ethnicity					
n	80	77	80	81	318
Hispanic or Latino	7 (8.8%)	5 (6.5%)	6 (7.5%)	3 (3.7%)	21 (6.6%)
Not Hispanic or Latino	71 (88.8%)	71 (92.2%)	74 (92.5%)	78 (96.3%)	294 (92.5%)
Not Available	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
Race					
n	80	77	80	81	318
American Indian or Alaska Native	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
Asian	3 (3.8%)	4 (5.2%)	6 (7.5%)	1 (1.2%)	14 (4.4%)
Black	10 (12.5%)	9 (11.7%)	9 (11.3%)	5 (6.2%)	33 (10.4%)
White	64 (80.0%)	62 (80.5%)	63 (78.8%)	74 (91.4%)	263 (82.7%)
Not Available	3 (3.8%)	2 (2.6%)	1 (1.3%)	(0.0%)	6 (1.9%)

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_demog)
Database (CLOSED) Datasets (pat)
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Table 8 Demographic and Baseline Characteristics: Modified Intent-to-Treat Population (cont.)

Genentech, Inc. Study q4881g
Xolair (Omalizumab) Xolair in Refractory Chronic Idiopathic Urticaria (CIU)

Table 14.1/6
Demographic and Baseline Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Weight (kg)					
n	80	77	80	81	318
Mean (SD)	83.0 (20.5)	81.1 (19.2)	83.2 (24.4)	81.6 (19.7)	82.2 (21.0)
Median	81.0	80.0	79.8	76.0	80.0
Range	50 - 138	50 - 134	35 - 138	53 - 134	35 - 138
Weight					
n	80	77	80	81	318
<80 kg	35 (43.8%)	38 (49.4%)	40 (50.0%)	45 (55.6%)	158 (49.7%)
>=80 kg	45 (56.3%)	39 (50.6%)	40 (50.0%)	36 (44.4%)	160 (50.3%)
BMI					
n	80	77	78	81	316
Mean (SD)	28.7 (6.2)	29.4 (6.5)	29.8 (7.7)	29.3 (6.9)	29.3 (6.8)
Median	27.9	28.4	29.0	27.2	28.3
Range	19 - 47	18 - 49	16 - 54	20 - 52	16 - 54

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_demog)
Database (CLOSED) Datasets (pat)
: Generated 25JAN13 13:59 Page 2 of 2

Baseline disease characteristics of the mITT population are summarized in Table 9. There was no major imbalance across treatment groups. Some differences were noted and include the following:

- The placebo group had a higher percentage of patients with a positive CU index test (31.3%) than the other treatment groups (23.4%, 20.3% and 25.9% of patients in the 75-mg, 150-mg and 300-mg groups, respectively).
- The placebo group also had a higher percentage of patients reporting the presence of angioedema at baseline (55.0%) than the other treatment groups (45.5%, 47.5% and 42.0% of patients in the 75-mg, 150-mg and 300-mg groups, respectively).
- The 75-mg omalizumab group had a higher percentage of patients with high levels of thyroperoxidase antibody (21.6%) than the other 3 groups (12.5%, 11.1% and 15.2% of patients in the 150-mg, 300-mg, and placebo groups, respectively).
- The 75-mg omalizumab group also had a higher percentage of patients with previous use of systemic steroids for CIU (53.2%) than the other 3 groups (40.0%, 44.4%, and 38.8% of patients in the 150-mg, 300-mg, and placebo groups, respectively).

The average duration of CIU at baseline was 6.9 years (median 3.7 years). Patients reported using, on average, 4.7 (range, 1–18) previous medications for CIU. The mean baseline weekly itch severity score was 14.3 (range, 8–21), while the mean baseline UAS7 was 31.1 (range, 16–42). The mean physician-assessed in-clinic UAS was 5.3 (range, 4–6). The mean baseline total IgE level in all patients was 182.8 IU/mL (median 83 IU/mL), with the following distribution: 195.3 IU/mL (median 91.0 IU/mL), 225.2 IU/mL (median 71.0 IU/mL), 152.6 IU/mL (median 85.5 IU/mL), and 161.5 IU/mL (median 92.0 IU/mL) for patients in the omalizumab 75-mg, 150-mg, 300-mg, and placebo groups, respectively. A positive CU index test result was present in 25.2% of patients at baseline, and 47.5% reported the presence of angioedema at baseline (during the week prior to the date of first treatment).

Table 9 Baseline Disease Characteristics: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Duration of CIU, in years					
n	78	76	78	81	313
Mean (SD)	7.0 (9.7)	7.0 (9.7)	7.6 (9.2)	6.2 (8.0)	6.9 (9.1)
Median	3.7	3.8	4.3	3.2	3.7
Range	0.5–48.2	0.5–50.5	0.5–44.4	0.5–35.4	0.5–50.5
Previous number of CIU medications					
n	80	77	80	81	318
Mean (SD)	5.0 (2.8)	4.7 (2.8)	4.5 (3.2)	4.5 (2.3)	4.7 (2.8)
Median	4.5	4.0	4.0	4.0	4.0
Range	1–13	1–13	1–18	1–10	1–18
Previous Use of Systemic Steroids for CIU					
n	80	77	80	81	318
Yes	31 (38.8%)	41 (53.2%)	32 (40.0%)	36 (44.4%)	140 (44.0%)
Positive CU index test, number (%) of patients [a]					
n	80	77	79	81	317
Yes	25 (31.3%)	18 (23.4%)	16 (20.3%)	21 (25.9%)	80 (25.2%)

Table 9 Baseline Disease Characteristics: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Total IgE level, in IU/mL					
n	77	75	74	80	306
Mean (SD)	161.5 (215.1)	195.3 (334.5)	225.2 (612.6)	152.6 (285.2)	182.8 (387.8)
Median	92.0	91.0	71.0	85.5	83.0
Range	1–1010	1–2030	1–5000	1–2330	1–5000
In-Clinic UAS [b]					
n	80	77	80	81	318
Mean (SD)	5.3 (0.8)	5.3 (0.8)	5.3 (0.7)	5.3 (0.8)	5.3 (0.8)
Median	5.0	5.0	5.0	5.0	5.0
Range	4–6	4–6	4–6	4–6	4–6
UAS7 [c]					
n	80	77	80	81	318
Mean (SD)	31.1 (6.7)	31.7 (6.7)	30.3 (7.3)	31.3 (5.8)	31.1 (6.6)
Median	31.5	31.5	30.8	31.5	31.5
Range	16.0–42.0	17.0–42.0	16.0–42.0	19.5–42.0	16.0–42.0

Table 9 Baseline Disease Characteristics: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Weekly itch severity score [c]					
n	80	77	80	81	318
Mean (SD)	14.4 (3.5)	14.5 (3.6)	14.1 (3.8)	14.2 (3.3)	14.3 (3.5)
Median	14.0	14.0	14.0	14.0	14.0
Range	8.0–21.0	8.5–21.0	8.0–21.0	8.0–21.0	8.0–21.0
<13	26 (32.5%)	28 (36.4%)	26 (32.5%)	28 (34.6%)	108 (34.0%)
≥13	54 (67.5%)	49 (63.6%)	54 (67.5%)	53 (65.4%)	210 (66.0%)
Weekly number of hives score [c]					
n	80	77	80	81	318
Mean (SD)	16.7 (4.4)	17.2 (4.2)	16.2 (4.6)	17.1 (3.8)	16.8 (4.3)
Median	18.3	19.0	17.0	18.5	18.5
Range	5.0–21.0	7.5–21.0	4.5–21.0	8.5–21.0	4.5–21.0
Presence of angioedema [c] number (%) of patients					
n	80	77	80	81	318
Yes	44 (55.0%)	35 (45.5%)	38 (47.5%)	34 (42.0%)	151 (47.5%)

Table 9 Baseline Disease Characteristics: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Level of thyroperoxidase antibody					
n	79	74	80	81	314
High (>34.99 U/mL)	12 (15.2%)	16 (21.6%)	10 (12.5%)	9 (11.1%)	47 (15.0%)
Normal (≤34.99 U/mL)	67 (84.8%)	58 (78.4%)	70 (87.5%)	72 (88.9%)	267 (85.0%)

CIU=chronic idiopathic urticaria; CU=chronic urticaria; SD=standard deviation; UAS=urticaria activity score; UAS7=UAS over 7 days.

[a] The CU index test reflects circulating histamine releasing factors in normal basophils, one of which is anti-FcεRI

[b] Baseline in-clinic UAS is defined as the largest value among the Day −14 screening visit, Day −7 screening visit, and Day 1 visit.

[c] Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: page 239

4.6 PREVIOUS AND CONCURRENT DISEASES AND TREATMENTS

The targeted medical history and baseline conditions assessed at screening are summarized on page 244. There was no major imbalance in previous and concurrent diseases among treatment groups. At baseline, all patients had currently active CIU, a criterion for entry into the study. More than a third of patients also reported currently active allergic rhinitis (ranging from 35% to 44% of patients across the four treatment groups) and close to 20% reported currently active asthma at baseline (ranging from 16% to 25% of patients across the four treatment groups). More than a third of patients reported a history of angioedema (ranging from 34% to 43% of patients across the four treatment groups) and approximately one quarter of the patients reported a history of hypertension (ranging from 24% to 29% of patients across the four treatment groups). Note that the presence of angioedema at baseline summarized in Table 9 was based on patient eDiary data during the 7 days before randomization and may be different from the angioedema status reported at screening.

All but 1 patient (Patient [redacted] in the omalizumab 150-mg group) in the study was previously treated with H1 antihistamines for CIU (see page 246, page 233, and page 234). Besides H1 antihistamines, the most frequently used prior medications for CIU were steroids (50% of patients), histamine H2-receptor antagonists (29.2%), LTRAs (26.1%) and hydroxyzine hydrochloride (30.5%) with similar percentages, in general, across treatment groups. In addition, there were 2 patients (Patient [redacted] in the placebo group and Patient [redacted] in the omalizumab 150-mg group) who received previous treatment for CIU with omalizumab more than 1 year prior to screening (see page 246). Patients [redacted] and [redacted] met the study's inclusion criteria and Patient [redacted] did not since this patient was not previously treated with H1 antihistamines for CIU.

At baseline, all but 3 patients (Patient [redacted] in the 75-mg group; Patients [redacted] and [redacted] in the omalizumab 150-mg group) were being treated for CIU with H1 antihistamines (see page 252, page 233, and page 234).

The concomitant medications started during the treatment period are summarized on page 272. New antihistamines, histamine H2-receptor antagonists, and steroids started during the treatment period are presented in Table 10. A total of 59 (18.6%) patients began a new medication for CIU during the 24-week treatment period and the most commonly used new medications were antihistamines (12.3% of patients) and steroids (5.7% of patients) (see page 272).

After last patient last visit and before study unblinding, the Medical Monitor reviewed the onset and duration of concomitant medications to identify patients who had received excluded therapies during the treatment period (see list of excluded mediations in Section 4.4.2 of the protocol on page 1443). Efficacy data observed on or after a patient started the excluded medication were considered missing and handled through use of the missing data handling rule (see SAP Section 4.7 on page 1689) unless otherwise

specified. The impact on the efficacy endpoints is summarized in Section 5.5.2. Safety data observed on or after a patient started the excluded medication were summarized as part of the follow-up period.

Table 10 Concomitant Medications: New Onset of Antihistamines, Histamine H2 receptor Antagonists, and Steroids during the Treatment Period: Modified Intent-to-Treat Population

Class of CIU Medication	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any medication use for CIU	19 (23.8%)	16 (20.8%)	16 (20.0%)	8 (9.9%)	59 (18.6%)
Antihistamines					
Overall [a]	11 (13.8%)	13 (16.9%)	10 (12.5%)	5 (6.2%)	39 (12.3%)
Histamine H2-receptor antagonists					
Overall	4 (5.0%)	0	1 (1.3%)	0	5 (1.6%)
Steroids					
Overall	8 (10.0%)	3 (3.9%)	5 (6.3%)	2 (2.5%)	18 (5.7%)

CIU=chronic idiopathic urticaria.

[a] New onsets of antihistamine treatment were either a different medication or a change in dose from baseline, including a stop and restart of the baseline H1 antihistamine.

Source: page 272.

The concomitant medications started during the follow-up period are summarized on (see page 291). During the follow-up period, 99 patients (31.1%) started new medications for CIU and the most commonly used new concomitant medications were antihistamines (23.9%) and steroids (13.2%).

5. RESULTS: EFFICACY

The efficacy results in this section are based on analyses that included all randomized and treated patients (mITT population) unless otherwise specified. Patients were analyzed according to their randomized treatment assignment. Any endpoint that consists of mean change from baseline at a particular timepoint (e.g., Week 12) was defined as the score at the particular timepoint minus the baseline score. Missing scores at a post-baseline timepoint were imputed using the baseline score (BOCF) in the analyses, unless otherwise specified.

All statements regarding statistical significance are in accordance with the overall type I error control plan as specified in the SAP.

5.1 OVERVIEW OF EFFICACY

The study met its primary efficacy endpoint with patients in each omalizumab dose group demonstrating statistically significant decreases from baseline in weekly itch severity scores at Week 12 relative to the placebo group. In addition, the following endpoints were met in the study by demonstrating statistically significant improvements in patients in the omalizumab groups (as specified below) compared with patients in the placebo group:

- All nine secondary efficacy endpoints for the 300-mg omalizumab group
- The first six secondary efficacy endpoints for the 150-mg omalizumab groups
- The first two secondary efficacy endpoints for the 75-mg omalizumab group

Greater efficacy was observed in the 300-mg omalizumab group relative to the 75 mg and 150 mg omalizumab groups for the primary endpoint and all of the secondary endpoints. The robustness of the primary efficacy results was supported by consistent findings from subgroup and sensitivity analyses. The treatment benefit of omalizumab on itch severity was consistent across subgroups based on a wide range of patient characteristics. Moreover, results from multiple exploratory efficacy endpoints were also consistent with the primary and secondary endpoints, in that they favored the omalizumab 300-mg group versus the placebo group.

A summary of key efficacy results is presented in Table 11. All p-values are relative to the placebo group.

Table 11 Summary of Key Efficacy Results: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Primary endpoint: Change from baseline to Week 12 in weekly itch severity score				
Mean (SD)	−3.63 (5.22)	−6.46 (6.14)	−6.66 (6.28)	−9.40 (5.73)
p-value (vs. placebo)	—	0.0010 [a]	0.0012 [a]	<0.0001 [a]
Secondary endpoints (Presented as per hierarchical testing):				
Change from baseline to Week 12 in UAS7				
Mean (SD)	−8.01 (11.47)	−13.82 (13.26)	−14.44 (12.95)	−20.75 (12.17)
p-value (vs. placebo)	—	0.0035 [a]	0.0008 [a]	<0.0001 [a]
Change from baseline to Week 12 in weekly number of hives score				
Mean (SD)	−4.37 (6.60)	−7.36 (7.52)	−7.78 (7.08)	−11.35 (7.25)
p-value (vs. placebo)	—	0.0149 [a]	0.0017 [a]	<0.0001
Time to MID response in weekly itch severity score by Week 12				
Median (weeks)	4.0	3.0	2.0	1.0
HR	—	1.39	1.49	2.34
p-value (vs. placebo)	—	0.0879	0.0301 [a]	<0.0001 [a]
Patients with UAS7 ≤6 at Week 12				
Number (%)	9 (11.3%)	20 (26.0%)	32 (40.0%)	42 (51.9%)
p-value (vs. placebo)	—	0.0148 [b]	<0.0001 [a]	<0.0001 [a]
Proportion of weekly itch severity score MID responders at Week 12				
Number (%)	29 (36.3%)	43 (55.8%)	45 (56.3%)	61 (75.3%)
p-value (vs. placebo)	—	0.0118 [b]	0.0226 [a]	<0.0001 [a]
Change from baseline to Week 12 in weekly size of largest hive score				
Mean (SD)	−3.93 (5.44)	−6.20 (6.29)	−6.96 (6.68)	−9.79 (6.66)
p-value (vs. placebo)	—	0.0124 [b]	0.0012 [a]	<0.0001 [a]
Change from baseline in overall DLQI at Week 12				
Mean (SD)	−6.13 (6.25)	−6.33 (6.08)	−8.00 (7.24)	−10.29 (7.23)
p-value (vs. placebo)	—	0.7956 [b]	0.2286	<0.0001 [a]

Table 11 Summary of Key Efficacy Results: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Proportion of angioedema free days from Week 4 to Week 12				
Mean (SD)	88.2% (19.4%)	86.5% (28.4%)	89.6% (20.6%)	96.1% (11.3%)
p-value (vs. placebo)	—	0.4867 [b]	0.1747 [b]	<0.0001 [a]
Proportion of Complete Responders (UAS7=0) at Week 12				
Mean (SD)	7 (8.8%)	9 (11.7%)	12 (15.0%)	29 (35.8%)
p-value (vs. placebo)	—	0.4580 [b]	0.2087 [b]	<0.0001 [a]

DLQI=Dermatology Life Quality Index; HR=hazard ratio; MID=minimally important difference; SD=standard deviation; UAS7=urticaria activity score over 7 days.

[a] Statistically significant according to the type I error control plan.

[b] Not evaluated for statistical significance in accordance with the type I error control plan

Source: page 307, page 308, page 309, page 310, page 311, page 312, page 313, page 314, page 315, page 316.

5.2 PRIMARY EFFICACY ENDPOINT

The primary endpoint assessed the change from baseline in weekly itch severity score at Week 12. The results from the analyses of the primary endpoint are summarized in Table 12. At Week 12, the mean weekly itch severity score decreased from baseline by 6.46 points in the omalizumab 75-mg group, 6.66 points in the omalizumab 150-mg group, and 9.40 points in the omalizumab 300-mg group compared with 3.63 points in the placebo group. The difference between each of the three omalizumab dose groups and the placebo group was statistically significant in favor of omalizumab ($p=0.0010$ for the omalizumab 75-mg group, $p=0.0012$ for the omalizumab 150-mg group and $p<0.0001$ for the omalizumab 300-mg group).

Table 12 Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method): Modified Intent-to-Treat Population

	Placebo (n = 80)	Omalizumab 75 mg (n = 77)	Omalizumab 150 mg (n = 80)	Omalizumab 300 mg (n = 81)
Change from Baseline in Weekly Itch Severity Score [a]				
Mean (SD)	−3.63 (5.22)	−6.46 (6.14)	−6.66 (6.28)	−9.40 (5.73)
Range	−18.5 to 7.5	−21.0 to 4.0	−21.0 to 5.0	−19.5 to 0.0
95% CI of the Mean	−4.80, −2.47	−7.85, −5.06	−8.05, −5.26	−10.66, −8.13
Treatment Difference in LS Means (vs. placebo) [b]	—	−2.96	−2.95	−5.80
95% CI of the LS Means Difference	—	−4.71, −1.21	−4.72, −1.18	−7.49, −4.10
p-value [c]	—	0.0010	0.0012	< 0.0001

ANCOVA = analysis of covariance; BOCF = baseline observation carried forward; CI = confidence interval; LS = least squares; SD = standard deviation.

Note: Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

[a] Weekly itch severity score is a component of the UAS7. Daily itch severity scores is the average of the morning and evening scores with use of a scale of 0 (none) to 3 (severe). Weekly itch severity score is the sum of the daily scores over 7 days; thus, the weekly score represents pruritus (itch) severity on a scale from 0 (minimum) to 21 (maximum).

[b] The LS means were estimated using an ANCOVA model. The strata are baseline weekly itch severity score (< 13, ≥ 13) and baseline weight (< 80 kg vs. ≥ 80 kg).

[c] p-value is derived from ANCOVA t-test.

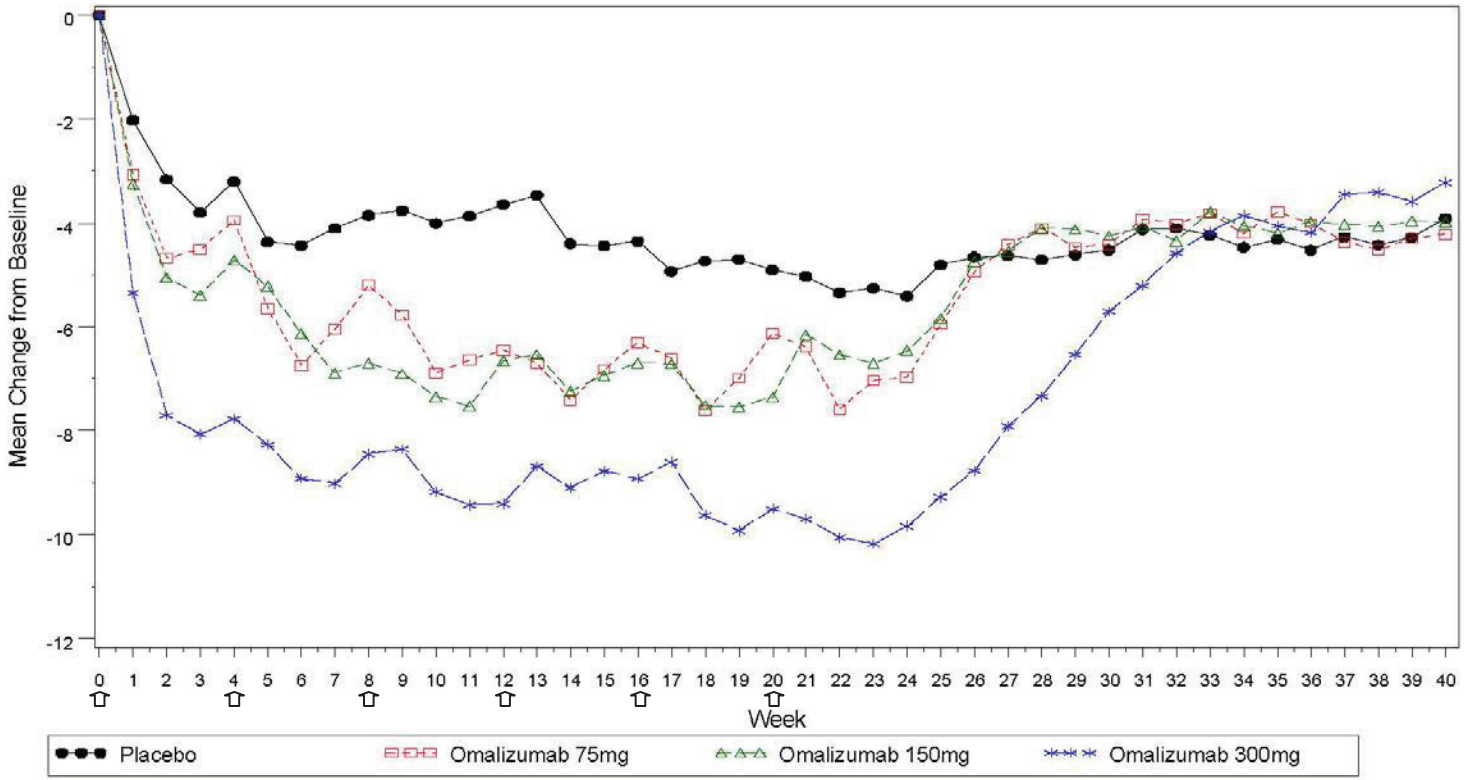
Source: page 307.

The mean change from baseline in weekly itch severity score by study week from Weeks 0 to 40 by treatment group is displayed in Figure 3. The mean weekly itch severity score decreased from baseline in all treatment groups during the 40-week study period (see page 317 and page 318). Patients in all three omalizumab dose groups had a greater mean decrease in weekly itch severity score than patients in the placebo group at all timepoints during the first 12 weeks of the treatment period. The means and mean changes from baseline in weekly itch severity score by study week are summarized on page 318. The mean weekly itch severity score decrease relative to mean placebo response was observed across all omalizumab treatment groups within 1 week of the first dose of omalizumab. At Week 1, the mean decreases from baseline in weekly itch severity score in the omalizumab 75-mg, 150-mg, and 300-mg groups were 3.07 points, 3.24 points, and 5.34 points, respectively, compared with 2.02 points in the placebo group. Across all timepoints in the first 24 weeks, the mean decrease from baseline in the weekly itch severity score for patients in the omalizumab 300-mg group was the greatest, followed by patients in the omalizumab 150-mg and omalizumab 75-mg groups (which had similar mean decreases from baseline over time), and then the placebo

group. No formal statistical comparisons were performed between the omalizumab groups.

After Week 24 (follow-up period), the mean weekly itch severity score increased to reach values similar to the placebo group mean values, and neither the placebo group nor any of the omalizumab groups returned to the baseline values for the duration of the follow-up period.

Figure 3 Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method): Modified Intent-to-Treat Population



Missing weekly scores are imputed using baseline weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Sensitivity analyses were performed on the primary endpoint to assess the robustness of the primary analysis results. The results from the ANCOVA where missing Week 12 scores were imputed using the LOCF method are summarized on page 325. Graphical summaries were also generated for the mean change from baseline in weekly itch severity score with use of the LOCF method to impute missing scores. The results were similar to those based on the BOCF imputation method (see page 326). The results from fitting a mixed effects model which included all observed weekly itch severity scores from baseline to Week 12 are summarized on page 327. The sensitivity analyses showed similar results to those of the primary analysis in which the BOCF method was used to impute missing Week 12 scores. In addition, an ANCOVA model was fitted, which was similar to the primary analysis but imputed the Week 12 weekly itch severity score by carrying forward the baseline weekly itch severity score (BOCF) for the 3 patients in the study with non-missing weekly itch severity scores at Week 12 who received systemic steroids during the 2 weeks prior to the Week 12 visit (Days 71 to 84) but for whom the duration of steroid treatment did not meet the criteria for excluded medication. The results from this sensitivity analysis were similar to the primary analysis results (see page 328).

5.3 SECONDARY EFFICACY ENDPOINTS

The secondary endpoints listed below follow the hierarchical order of the secondary endpoints in the type I error control plan.

5.3.1 Change from Baseline in UAS7 at Week 12

The results from the analysis of the change from baseline in UAS7 at Week 12 are summarized in Table 13. At Week 12, the mean UAS7 decreased from baseline by 13.82, 14.44, and 20.75 points in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 8.01 points in the placebo group. The difference between each of the three omalizumab dose groups and the placebo group was statistically significant in favor of omalizumab and followed a dose-dependent pattern as shown in Table 13.

Table 13 Change from Baseline in UAS7 at Week 12 (BOCF Method): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from Baseline in UAS7 [a]				
Mean (SD)	−8.01 (11.47)	−13.82 (13.26)	−14.44 (12.95)	−20.75 (12.17)
Range	−39.0 to 14.5	−42.0 to 7.0	−40.0 to 4.5	−40.0 to 1.0
95% CI of the Mean	−10.56, −5.45	−16.83, −10.81	−17.32, −11.55	−23.44, −18.06
Treatment Difference in LS Means (vs. placebo) [b]	—	−5.75	−6.54	−12.80
95% CI of the LS Means Difference	—	−9.59, −1.92	−10.33, −2.75	−16.44, −9.16
p-value [c]	—	0.0035	0.0008	<0.0001

ANCOVA=analysis of covariance; BOCF=baseline observation carried forward; CI=confidence interval; LS=least squares; SD=standard deviation; UAS7=urticaria activity score over 7 days.

Note: Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

[a] The UAS is a composite of recorded score with numeric severity intensity ratings on a scale of 0–3 (0=none to 3=intense/severe) for 1) the number of wheals (hives); and 2) the intensity of the itch, measured twice daily (morning and evening). Daily UAS is the average of morning and evening scores (range, 0–6 points/day) and the UAS7 is the sum of the daily UAS scores over 7 days (range, 0–42).

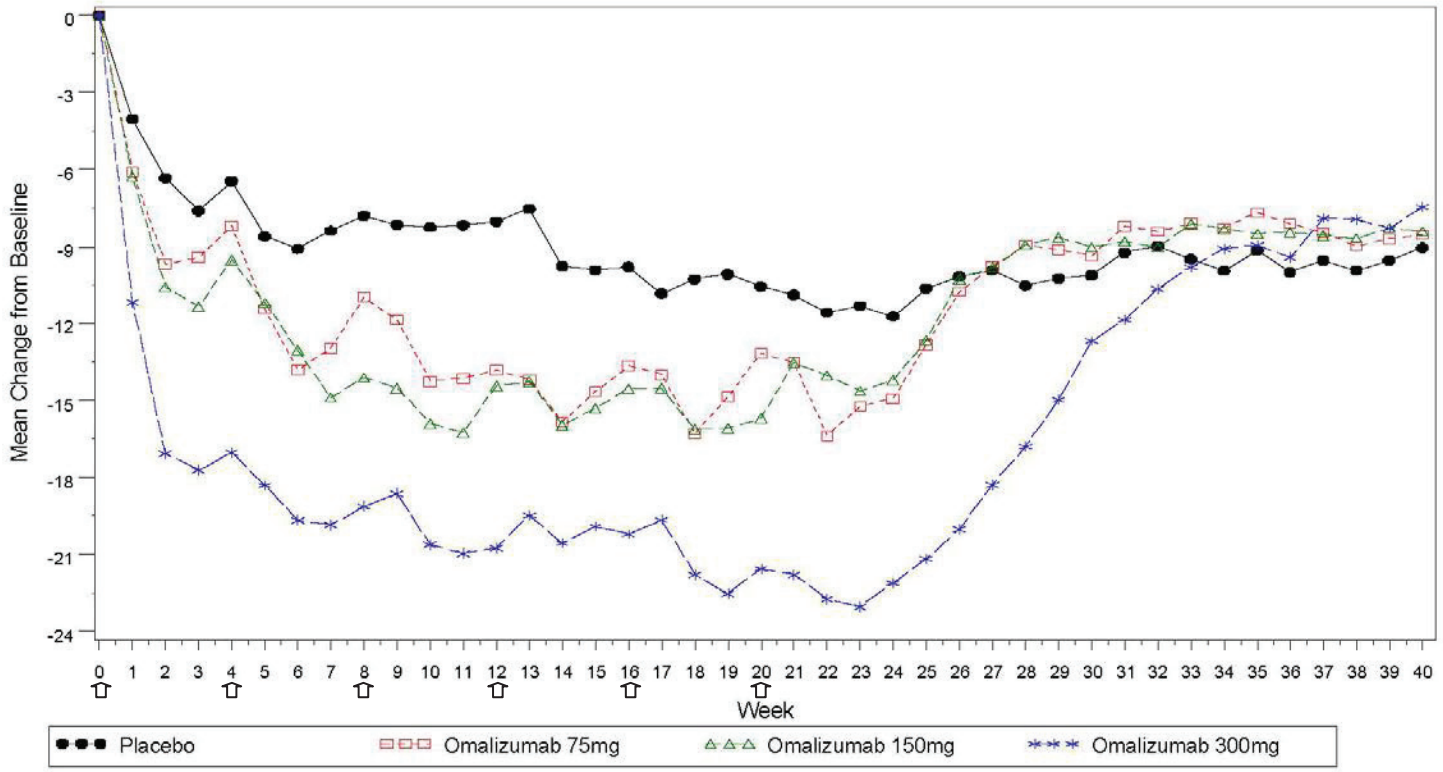
[b] The LS mean was estimated using an ANCOVA model. The strata/covariates are baseline UAS7 (<median vs. ≥median), and baseline weight (<80 kg vs. ≥80 kg).

[c] p-value is derived from ANCOVA t-test.

Source: page 308.

The mean change from baseline in UAS7 by study week (from Weeks 0 to 40) and by treatment group is plotted in Figure 4. The pattern of the curves representing the mean decrease in UAS7 from baseline appears to be similar to that observed for the mean change from baseline in weekly itch severity score over time. The means and mean change from baseline and UAS7 by study week are presented on page 329 and page 336. After Week 24 (follow-up period), the mean UAS7 increased to reach values similar to placebo group mean values and neither the placebo group nor any of the omalizumab groups returned to the baseline values for the duration of the follow-up period. A similar plot was generated for the mean change from baseline in UAS7 using the LOCF method to impute missing scores. The results appear to be similar to those based on BOCF imputation method (see page 337).

Figure 4 Mean Change from Baseline in UAS7 by Study Week (BOCF Method): Modified Intent-to-Treat Population



⇧ Omalizumab or placebo injection day

Missing weekly scores are imputed using baseline weekly scores.
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Database (CLOSED) Datasets (diaryeff)
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5.3.2 Change from Baseline in Weekly Number of Hives Score at Week 12

The results of the analysis of the change from baseline in weekly number of hives score at Week 12 are summarized in Table 14. At Week 12, the mean weekly number of hives score decreased from baseline by 7.36, 7.78, and 11.35 points in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 4.37 points in the placebo group. The difference between each of the three omalizumab groups and the placebo group at Week 12 was statistically significant in favor of omalizumab and followed a dose-dependent pattern as shown in Table 14.

Table 14 Change from Baseline in Weekly Number of Hives Score at Week 12 (BOCF Method): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from Baseline in Weekly Number of Hives Score [a]				
Mean (SD)	−4.37 (6.60)	−7.36 (7.52)	−7.78 (7.08)	−11.35 (7.25)
Range	−21.0 to 7.3	−21.0 to 5.5	−21.0 to 2.1	−21.0 to 3.0
95% CI of the Mean	−5.84, −2.90	−9.07, −5.66	−9.36, −6.20	−12.96, −9.75
Treatment Difference in LS Means (vs. placebo) [b]	—	−2.75	−3.44	−6.93
95% CI of the LS Means Difference	—	−4.95, −0.54	−5.57, −1.32	−9.10, −4.76
p-value [c]	—	0.0149	0.0017	<0.0001

ANCOVA=analysis of covariance; BOCF=baseline observation carried forward; CI=confidence interval; LS=least squares; SD=standard deviation.

Note: Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

[a] Number of hives is measured twice daily (morning and evening), on a scale from 0 (none) to 3 (>12 hives per 12 hours). Daily hives score is the average of morning and evening scores, and the weekly hives score is the sum of the daily hives scores over 7 days (range, 0–21).

[b] The LS mean was estimated using an ANCOVA model. The strata are baseline weekly number of hives score (<median vs. ≥median), and baseline weight (<80 kg vs. ≥80 kg).

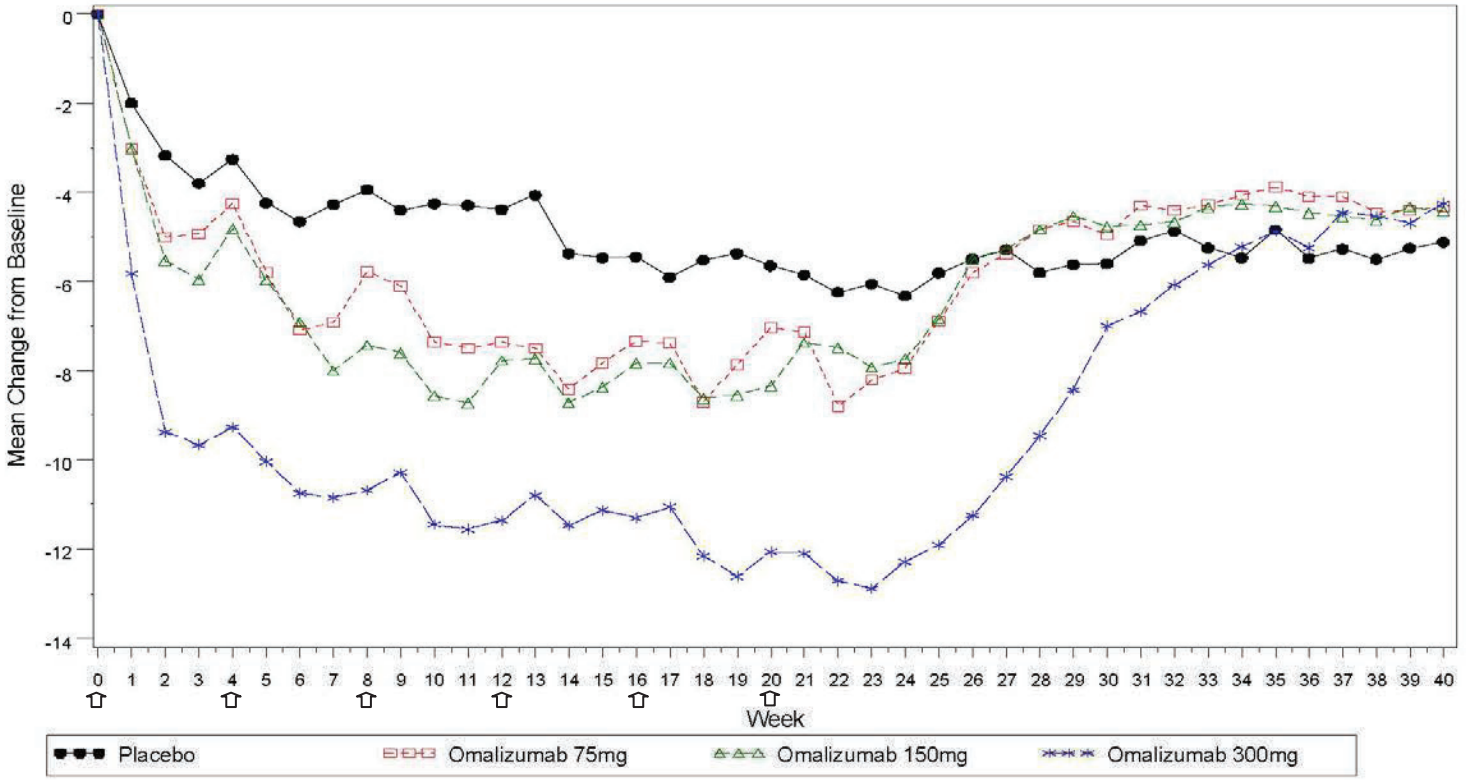
[c] p-value is derived from ANCOVA t-test.

Source: page 309.

The mean change from baseline in weekly number of hives score over time up to 40 weeks is plotted by treatment group in Figure 5. The pattern of the curves representing the mean decrease from baseline in weekly number of hives score appears to be similar to that observed for the change over time from baseline in weekly itch severity score. The means and mean change from baseline in weekly number of hives score by study week are presented on page 338, and page 345. After Week 24 (follow-up period), the mean weekly number of hives score increased to reach values similar to

placebo group values and neither the placebo group nor any of the omalizumab groups returned to the baseline values for the duration of the follow-up period. A similar plot was generated for the mean change from baseline in weekly number of hives score using the LOCF method to impute missing scores. The results appear to be similar to those based on the BOCF imputation method (see page 346).

Figure 5 Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method): Modified Intent-to-Treat Population



⇧ Omalizumab or placebo injection day

Missing weekly scores are imputed using baseline weekly scores.
Source: Biostatistics(r[redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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5.3.3 Time to Minimally Important Difference Response in Weekly Itch Severity Score by Week 12

The MID response for weekly itch severity score was defined as a reduction from baseline in weekly itch severity score of ≥ 5 points. The time to weekly itch severity score MID response was defined as the time (in weeks) from Day 1 to the first study week when weekly itch severity score MID response was achieved. For patients who did not experience an MID response by Week 12, time to MID response was censored at the week of the last non-missing weekly itch severity score evaluation up to Week 12. If a patient discontinued treatment prior to Week 12 without experiencing an MID response, the time to response was censored as of the treatment discontinuation date (as specified in Section 4.4.1 of the SAP on page 1673).

The results of the analysis of time to MID response in weekly itch severity score up to Week 12 are summarized in Table 15. By Week 12, 74.0%, 82.5%, and 93.8% of patients had a MID response in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 71.3% of patients in the placebo group. The median times to reach MID in weekly itch severity score were 3 weeks, 2 weeks, and 1 week for patients in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 4 weeks for patients in the placebo group. Compared with placebo, a statistically significant decrease in the duration of time to MID response was observed for patients in the omalizumab 150-mg group ($p = 0.0301$) and the omalizumab 300-mg group ($p < 0.0001$). The time to MID response in weekly itch severity score up to Week 12 for patients in the omalizumab 75-mg was not statistically significant compared with patients in the placebo group ($p = 0.0879$). Kaplan-Meier curves representing the times to MID response in weekly itch severity score by Week 12 are provided in Figure 6 for each treatment group.

Table 15 Time (Weeks) to Minimally Important Difference Response in Weekly Itch Severity Score up to Week 12: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Number of patients who reached MID [a] (%)	57 (71.3%)	57 (74.0%)	66 (82.5%)	76 (93.8%)
Time to MID response (weeks) [b, c]				
Median	4.0	3.0	2.0	1.0
95% CI [d]	2.0, 6.0	2.0, 5.0	2.0, 3.0	1.0, 2.0
Minimum, maximum	1.0, 12.0+	0.0+, 12.0+	1.0, 12.0+	0.0+, 12.0+
Hazard ratio (vs. placebo) [e]	—	1.39	1.49	2.34
95% CI	—	0.95, 2.03	1.04, 2.14	1.63, 3.36
p-value	—	0.0879	0.0301	<0.0001

CI=confidence interval; MID=minimally important difference; + =censored value.

[a] Weekly itch score MID response is defined as a reduction of ≥5 points from baseline in weekly itch score.

[b] Time (in weeks) from the date of the first dose to the date where weekly itch score MID response is first achieved.

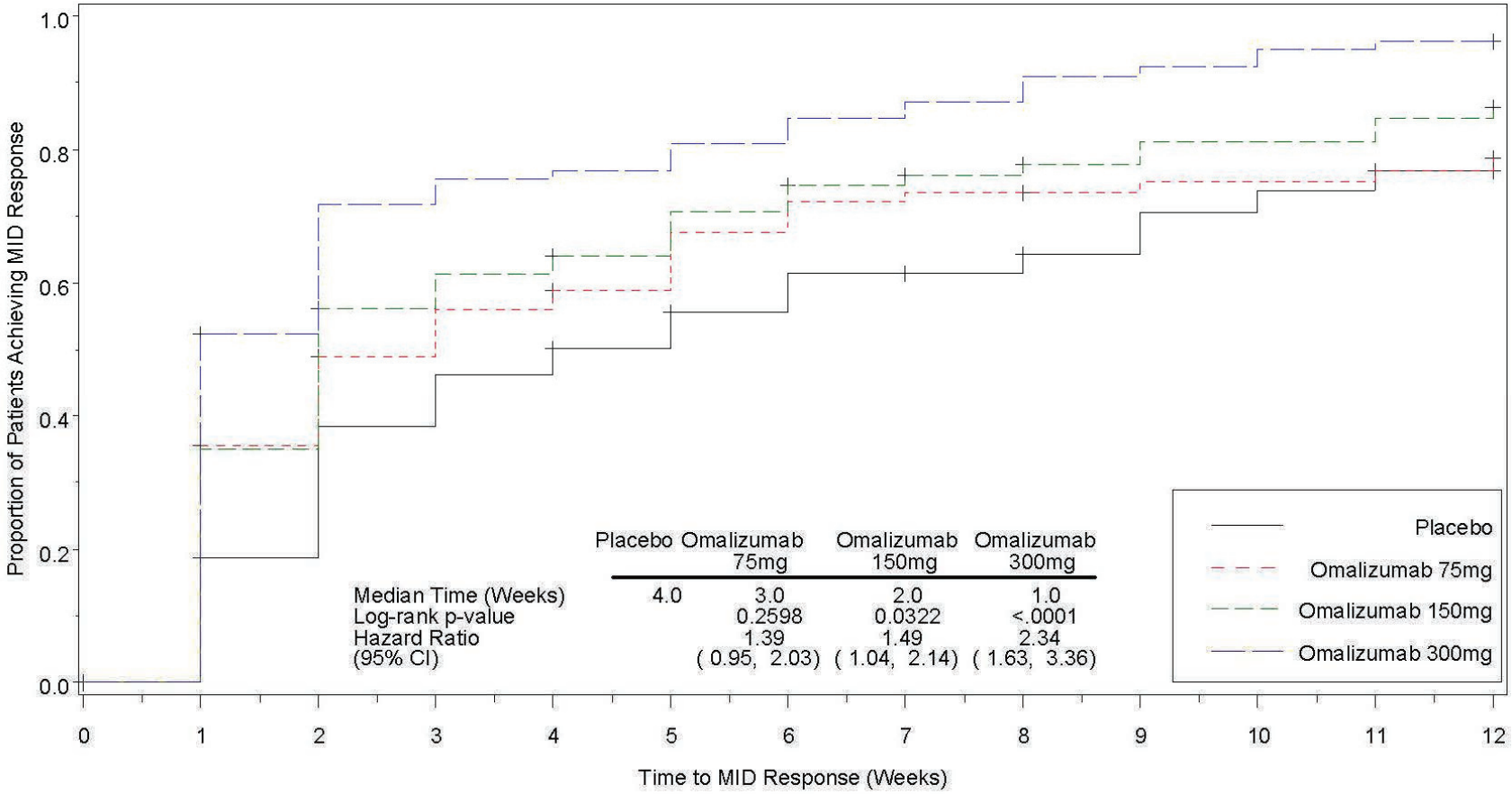
[c] Summaries based on Kaplan-Meier estimates.

[d] Computed using the method of Brookmeyer and Crowley.

[e] Hazard ratios estimated using Cox proportional hazards models stratified by baseline weekly itch severity score (<13, ≥13), and baseline weight (<80 kg vs. ≥80 kg).

Source: page 310.

Figure 6 Time (Weeks) to Minimally Important Difference Response in Weekly Itch Severity Score by Week 12: Modified Intent-to-Treat Population



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5.3.4 Proportion of Patients with UAS7 ≤6 at Week 12

UAS7 ≤6 identifies patients whose conditions are considered clinically well controlled. The proportion of patients who achieved UAS7 ≤6 at Week 12 is summarized in Table 16. If a patient discontinued treatment before Week 12 or if the UAS7 score was missing at Week 12, the Week 12 UAS7 was imputed to be >6; that is, patients with missing scores at Week 12 were assumed to be nonresponders. At Week 12, 26.0%, 40.0%, and 51.9% of patients achieved UAS7 ≤6 in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 11.3% of patients in the placebo group. The differences in the proportions of patients achieving UAS7 ≤6 at Week 12 between each of the omalizumab 150-mg and 300-mg groups and the placebo group were statistically significant in favor of omalizumab ($p<0.0001$ for the omalizumab 150-mg group and $p<0.0001$ for the omalizumab 300-mg group). The difference between the omalizumab 75-mg and placebo groups was not evaluated for statistical significance in accordance with the type I error control plan.

Table 16 Patients with UAS7 ≤ 6 at Week 12: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Week 12 UAS7 [a] ≤6	9 (11.3%)	20 (26.0%)	32 (40.0%)	42 (51.9%)
p-value (vs. placebo) [b]	—	0.0148	<0.0001	<0.0001

UAS7 = urticaria activity score over 7 days.

Note: If a patient discontinued treatment before Week 12, the patient will be counted as Week 12 UAS7 >6.

[a] The UAS is a composite of recorded scores with numeric severity intensity ratings on a scale of 0 (none) to 3 (intense/severe) for 1) the number of wheals (hives) and 2) the intensity of the itch, measured twice daily (morning and evening). Daily UAS is the average of morning and evening scores (range, 0–6 points per day) and the UAS7 is the sum of the daily UAS scores over 7 days (range, 0–42)

[b] p-value derived from the Cochran-Mantel-Haenszel test stratified by baseline UAS7 (<median vs. ≥median) and baseline weight (<80 kg vs. ≥80 kg).

Source: page 311

5.3.5 Proportion of Weekly Itch Severity Score MID Responders at Week 12

The proportion of patients who had a weekly itch severity score MID response at Week 12, defined as a reduction from baseline in weekly itch severity score of ≥5 points, is summarized in Table 17. If a patient discontinued treatment before Week 12 or if the weekly itch severity score was missing at Week 12, the patient was assumed to be a non-responder. At Week 12, 55.8%, 56.3%, and 75.3% of patients had a weekly itch severity score MID response in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 36.3% of patients in the placebo group. The differences between each of the omalizumab 150-mg and 300-mg groups and the placebo group in

proportions of MID responders at Week 12 were statistically significant in favor of omalizumab ($p = 0.0226$ for the 150-mg group and $p < 0.0001$ for the 300-mg group). The difference between the omalizumab 75-mg and placebo groups was not evaluated for statistical significance in accordance with the type I error control plan.

Table 17 Patients with Weekly Itch Severity Score Minimally Important Difference Response at Week 12: Modified Intent-to-Treat Population

Change from baseline in weekly itch severity score at Week 12	Placebo (n = 80)	Omalizumab 75 mg (n = 77)	Omalizumab 150 mg (n = 80)	Omalizumab 300 mg (n = 81)
≤ -5 [a]	29 (36.3%)	43 (55.8%)	45 (56.3%)	61 (75.3%)
p-value (vs. placebo) [b]	—	0.0118	0.0226	< 0.0001

MID = Minimally Important Difference.

[a] Weekly itch score MID response is defined as a reduction from baseline in weekly itch score of ≥ 5 points

[b] p-value is derived from the Cochran-Mantel-Haenszel test stratified by baseline weekly itch severity score (< 13, ≥ 13), and baseline weight (< 80 kg vs. ≥ 80 kg).

Source: page 312.

5.3.6 Change from Baseline in Weekly Size of the Largest Hive Score at Week 12

The results of the analysis of the change from baseline in weekly size of the largest hive score at Week 12 are summarized in Table 18. At Week 12, the mean weekly size of largest hive score decreased from baseline by 6.20, 6.96, and 9.79 points in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 3.93 points in the placebo group. The differences in change from baseline in weekly largest hive score at Week 12 between each of the omalizumab 150-mg and 300-mg groups and the placebo group were statistically significant in favor of omalizumab ($p = 0.0012$ for the 150-mg group and $p < 0.0001$ for the 300-mg group). The difference between the omalizumab 75-mg and placebo groups was not evaluated for statistical significance in accordance with the type I error control plan. Mean and mean change from baseline in weekly size of largest hive score by study week are presented on page 347.

Table 18 Change from Baseline in Weekly Size of Largest Hive Score at Week 12 (BOCF Method): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from baseline in weekly size of largest hive score [a]				
Mean (SD)	−3.93 (5.44)	−6.20 (6.29)	−6.96 (6.68)	−9.79 (6.66)
Range	−21.0 to 4.0	−21.0 to 2.0	−21.0 to 2.5	−21.0 to 3.0
95% CI of the Mean	−5.15, −2.72	−7.63, −4.78	−8.45, −5.48	−11.26, −8.32
Treatment difference in LS means (vs. placebo) [b]	—	−2.34	−3.16	−5.73
95% CI of the LS means difference	—	−4.17, −0.51	−5.05, −1.27	−7.59, −3.87
p-value [c]	—	0.0124	0.0012	<0.0001

ANCOVA=analysis of covariance; BOCF=baseline observation carried forward; CI=confidence interval; LS=least squares; SD=standard deviation.

Note: Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

[a] Measured twice daily, on a scale of 0 (none) to 3 (>2.5 cm). Daily largest hive score is the average of the morning and evening scores, and the weekly largest hive score is the sum of the daily scores over 7 days (range, 0–21).

[b] The LS mean was estimated using an ANCOVA model. The strata/covariates are baseline weekly size of largest hive score (< median vs. ≥ median), and baseline weight (< 80 kg vs. ≥ 80 kg).

[c] p-value is derived from ANCOVA t-test.

Source: page 313

5.3.7 Change from Baseline in Overall Dermatology Life Quality Index at Week 12

Overall DLQI scores have a range of 0–30; the higher the score, the more quality of life is impaired (Finlay and Khan 1994). The results of the analysis of the change from baseline in overall DLQI score at Week 12 are summarized in Table 19. The means and mean changes from baseline for the overall DLQI score and the DLQI sub domain scores are summarized on page 354. No imputation was performed for missing overall DLQI scores at Week 12. At Week 12, the mean overall DLQI decreased from baseline by 6.33, 8.00, and 10.29 points in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 6.13 points in the placebo group. The difference between the omalizumab 300-mg group and the placebo group was statistically significant in favor of omalizumab (p<0.0001 for the 300-mg group). The mean change from baseline in overall DLQI score at Week 12 in the omalizumab 150-mg was not statistically significant compared with the placebo group (p=0.2286) and the difference between the omalizumab 75-mg and placebo groups was not evaluated for statistical significance in accordance with the type I error control plan.

Table 19 Change from Baseline in Overall Dermatology Life Quality Index Score at Week 12 (Observed Data): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from Baseline in Overall DLQI [a] Score at Week 12				
n	62	66	63	72
Mean (SD)	−6.13 (6.25)	−6.33 (6.08)	−8.00 (7.24)	−10.29 (7.23)
Range	−24.0 to 9.0	−24.0 to 8.0	−30.0 to 9.0	−26.0 to 5.0
95% CI of the Mean	−7.72, −4.54	−7.83, −4.84	−9.82, −6.18	−11.99, −8.59
Treatment Difference in LS Means (vs. placebo) [b]	—	0.26	−1.31	−4.08
95% CI of the LS Means Difference	—	−1.76, 2.28	−3.46, 0.84	−5.96, −2.20
p-value [c]	—	0.7956	0.2286	<0.0001

DLQI=Dermatology Life Quality Index; LS=least squares.

Notes: Baseline overall DLQI score is the measurement taken prior to dosing on Day 1. No imputation for missing Week 12 scores.

[a] The DLQI questionnaire is a 10-item dermatology-specific health-related quality-of-life measure. Overall DLQI score is calculated by summing the score of each question and has a range of 0–30; the higher the score, the more quality of life is impaired (Finlay and Khan 1994).

[b] The LS mean was estimated using an ANCOVA model. The strata are baseline overall DLQI score (<median vs. ≥median), and baseline weight (<80 kg vs. ≥80 kg).

[C] p-value is derived from ANCOVA t-test.

Source: page 314.

5.3.8 Proportion of Angioedema-Free Days from Week 4 to Week 12

The proportion of angioedema-free days from Weeks 4 to 12 was defined as the number of days for which a patient responded “No” to the angioedema question in the daily diary divided by the total number of days with a non-missing diary entry, starting on the Week 4 visit date and ending the day prior to the Week 12 visit date. Patients who withdrew before the Week 4 visit or who had missing responses for >40% of the daily diary entries between the Week 4 study visit and the Week 12 study visit were not included in this analysis. No imputations were performed for missing data.

The results of the analysis of the proportion of angioedema-free days from Weeks 4 to 12 of therapy are summarized in Table 20. The mean proportion of angioedema-free days from Weeks 4 to 12 was 86.5%, 89.6%, and 96.1% in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 88.2% in the placebo group. The difference between the omalizumab 300-mg and the placebo groups in mean proportion of angioedema-free days from Week 4 to Week 12 was statistically significant in favor of omalizumab (p<0.0001). The differences between each of the omalizumab

150-mg and 75-mg groups and the placebo group were not evaluated for statistical significance in accordance with the type I error control plan.

Table 20 Proportion of Angioedema-Free Days from Week 4 to Week 12 of Therapy: Modified Intent-to-Treat Population

Proportion of Angioedema-Free Days from Week 4 to Week 12 [a]	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
n	66	69	70	74
Mean (SD)	88.2% (19.4%)	86.5% (28.4%)	89.6% (20.6%)	96.1% (11.3%)
Median	98.1%	100.0%	100.0%	100.0%
Range	2.0%–100.0%	0.0%–100.0%	0.0%–100.0%	23.2%–100.0%
95% CI of the Mean	83.5%, 93.0%	79.7%, 93.4%	84.7%, 94.5%	93.5%, 98.7%
p-value (vs. placebo) [b]	—	0.4867	0.1747	<0.0001

[a] Number of days for which the patient responded "No" to the angioedema question in the daily diary, divided by the total number of days with a nonmissing diary entry starting on the Week 4 visit and ending the day prior to the Week 12 visit. Patients who withdrew before the Week 4 visit or who have missing responses for >40% of the daily diary entries between the Week 4 visit and the Week 12 visit were not included in this analysis.

[b] p-value is derived from stratified Wilcoxon test. Stratification variables are presence of angioedema at baseline (yes vs. no) and baseline weight (<80 kg vs. ≥80 kg).

Source: page 315.

5.3.9 Proportion of Patients with Complete Response (UAS7=0) at Week 12

The proportions of patients who achieved a complete response at Week 12, defined as a UAS7=0, is summarized in Table 21. If a patient discontinued treatment before Week 12 or if the UAS7 was missing at Week 12, the patient was assumed to be a non-responder. At Week 12, 11.7%, 15.0%, and 35.8% of patients achieved a complete response in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 8.8% of patients in the placebo group. The difference between the omalizumab 300-mg group and the placebo group in proportion of complete responders at Week 12 was statistically significant in favor of omalizumab (p<0.0001). The differences between each of the omalizumab 75-mg and 150-mg groups and the placebo group were not evaluated for statistical significance in accordance with the type I error control plan.

Table 21 Patients with Complete Response (UAS7 = 0) at Week 12: Modified Intent-to-Treat Population

Complete Response (UAS7 = 0) [a]	Placebo (n = 80)	Omalizumab 75 mg (n = 77)	Omalizumab 150 mg (n = 80)	Omalizumab 300 mg (n = 81)
Week 12 UAS7 [a] = 0	7 (8.8%)	9 (11.7%)	12 (15.0%)	29 (35.8%)
p-value (vs. placebo) [b]	—	0.4580	0.2087	< 0.0001

Note: If a patient discontinued treatment before Week 12, the patient will be counted as non-responder.

[a] The UAS is a composite of recorded score with numeric severity intensity ratings on a scale of 0 – 3 (0 = none to 3 = intense/severe) for 1) the number of wheals (hives); and 2) the intensity of the itch, measured twice daily (morning and evening). Daily UAS is the average of morning and evening scores (range, 0–6 points/day) and the UAS7 is the sum of the daily UAS scores over 7 days (range, 0–42).

[b] p-value is derived from the Cochran-Mantel-Haenszel test stratified by baseline UAS7 (< median vs. ≥ median), and baseline weight (< 80 kg vs. ≥ 80 kg).

Source: page 316.

5.4 SUBGROUP AND EXPLORATORY ANALYSES

The subgroup and exploratory analyses were not included in the overall type I error control plan; therefore, the p-values presented in this section should be viewed as exploratory and should be interpreted with caution.

5.4.1 Subgroup Analyses

The subgroups assessed are listed in Section 3.8.3.5. Subgroup analyses for the change from baseline in weekly itch severity score at Week 12 (the primary efficacy endpoint) were performed and are presented schematically in Figure 7, Figure 8, and Figure 9 and in tables on page 368, page 369, page 371, page 373, page 374, page 375, page 376, page 377, page 378, page 379, page 380, page 381, page 383. Across the examined subgroups for all three omalizumab doses, the treatment effect of omalizumab versus placebo was generally consistent with the overall primary analyses results.

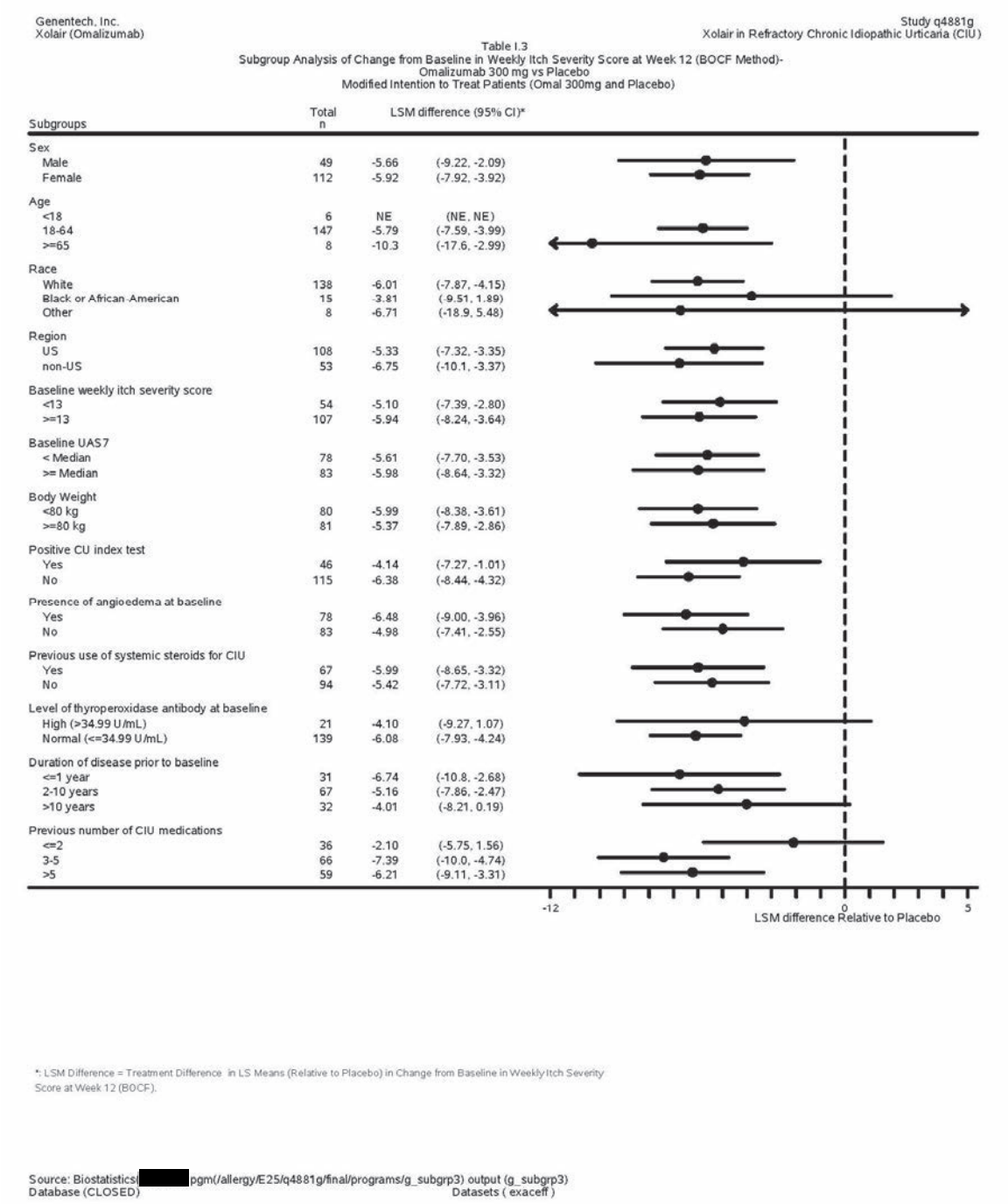
Because of the small sample size involved, the results of the following subgroups should be interpreted with caution:

- Age < 18 years old
- Age ≥ 65 years old
- Black or African American race
- Other race

Itch severity improvement (the decrease from baseline in weekly itch severity score) at Week 12 appeared to be associated with baseline weekly itch severity score. Across the four treatment groups, patients with higher baseline weekly itch severity scores (≥ 13) had larger absolute decreases from baseline in itch severity scores compared with

patients with lower baseline weekly itch severity scores (<13). The observed treatment effect (compared to placebo) across all three omalizumab dose groups was larger for patients with higher baseline weekly itch severity scores than for patients with lower baseline weekly itch severity scores (see page 374). Similarly, itch severity improvement appeared to be associated with baseline UAS7 (see page 375).

Figure 7 Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method): Omalizumab 300 mg vs. Placebo



NE = not evaluable

Figure 8 Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method): Omalizumab 150 mg vs. Placebo

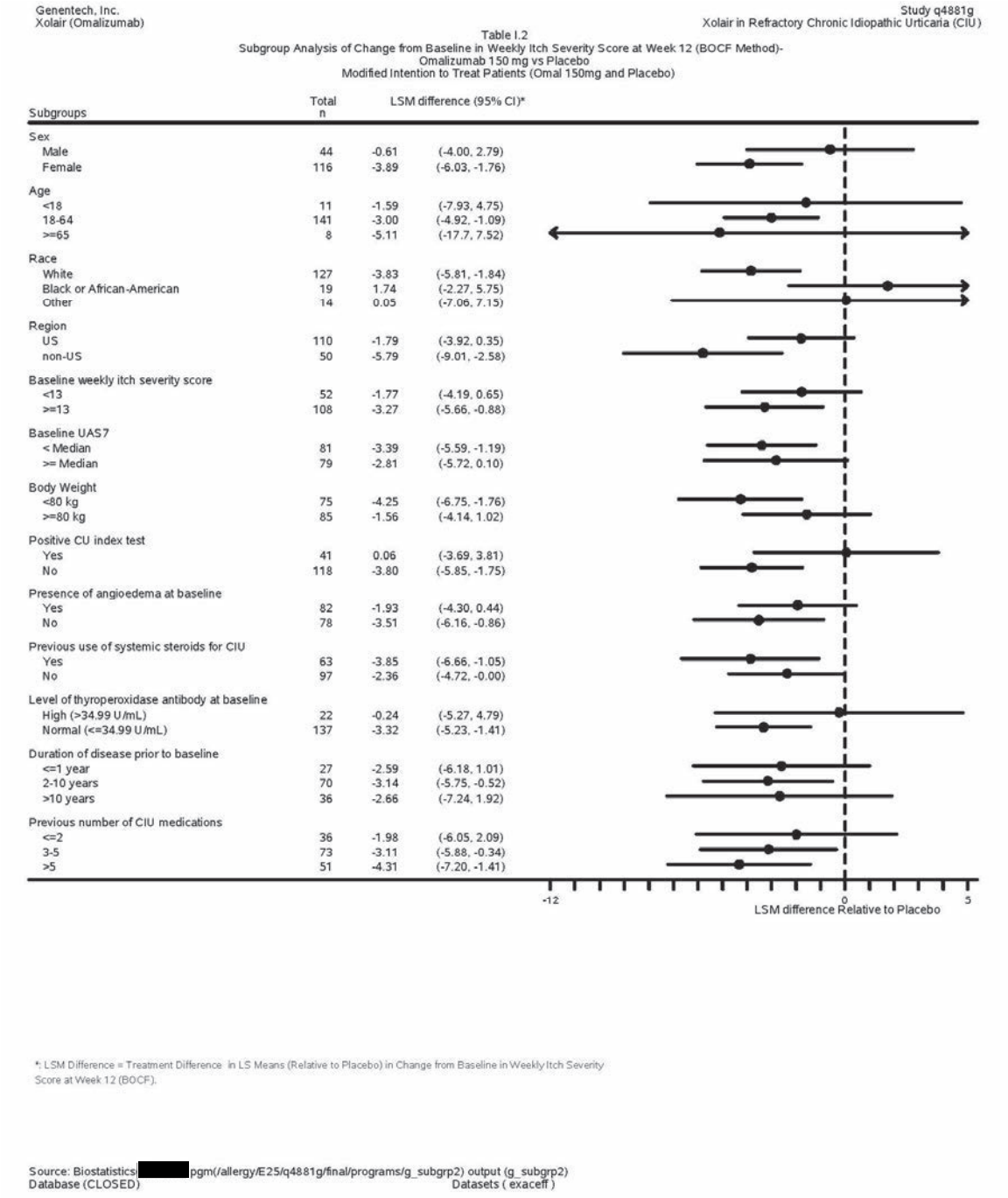
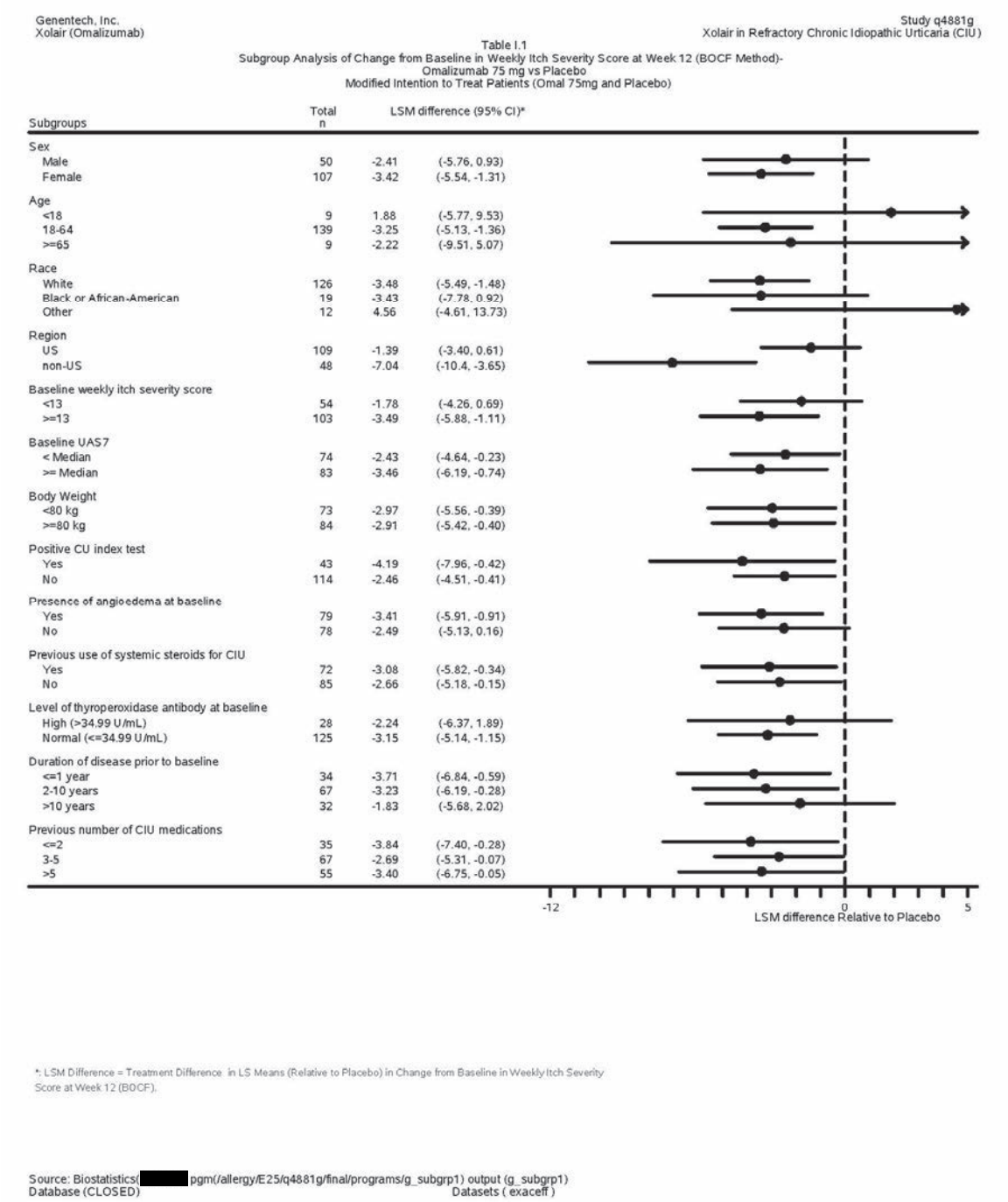


Figure 9 Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method): Omalizumab 75 mg vs. Placebo



*: LSM Difference = Treatment Difference in LS Means (Relative to Placebo) in Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF).

Source: Biostatistics/[redacted] pgm(/allergy/E25/q4881g/final/programs/g_subgrp1) output (g_subgrp1)
Database (CLOSED) Datasets (exaceff)

5.4.2 Exploratory Endpoints Up to the End of Treatment Period (Week 24)

Table 22 summarizes the results of the analyses of exploratory endpoints up to Week 12. In general, the results of the analyses of the exploratory endpoints were consistent with the results from the primary and secondary analyses endpoints with respect to the omalizumab treatment effect in in all three doses, except for inconsistent results among the nine MOS Sleep Scale domain scores. The results of these analyses consistently favored the omalizumab 300-mg group compared to the placebo group.

Table 22 Exploratory Endpoints Up to Week 12: Modified Intent-to-Treat Population

	Placebo (n = 80)	Omalizumab 75 mg (n = 77)	Omalizumab 150 mg (n = 80)	Omalizumab 300 mg (n = 81)
Time to UAS7 MID response [a] by Week 12				
Number of patients who reached MID (%)	50 (62.5%)	56 (72.7%)	62 (77.5%)	73 (90.1%)
Median time to MID response (weeks) [b]	6.0	3.0	3.0	1.5
Hazard ratio (vs. placebo)	—	1.52	1.67	2.69
95% CI		1.03, 2.24	1.15, 2.44	1.86, 3.90
p-value	—	0.0352	0.0077	<0.0001
Change from baseline in the proportion of itch-free days at Week 12 (BOCF) [c, d]				
Mean (SD)	14.4% (30.7%)	27.0% (37.2%)	33.3% (41.4%)	49.5% (44.8%)
p-value (vs. placebo)	—	0.0231	0.0014	<0.0001
Change from baseline in the proportion of hive-free days at Week 12 (BOCF) [e, d]				
Mean (SD)	15.5% (32.0%)	26.2% (36.7%)	34.2% (42.3%)	52.1% (46.4%)
p-value (vs. placebo)	—	0.0555	0.0020	<0.0001
Change from baseline in the proportion of itch-free and hive-free days at Week 12 (BOCF) [f, d]				
Mean (SD)	13.7% (30.4%)	24.3% (35.5%)	31.9% (40.6%)	46.6% (45.6%)
p-value (vs. placebo)	—	0.0486	0.0019	<0.0001
Change from baseline in weekly sleep interference score [g] at Week 12				
Mean (SD)	−3.86 (5.07)	−5.85 (5.78)	−5.63 (6.09)	−8.67 (5.80)
p-value (vs. placebo)	—	0.0345	0.0532	<0.0001
Change from baseline in weekly interference with daily activities score [h] at Week 12				
Mean (SD)	−3.82 (5.53)	−5.98 (6.16)	−6.35 (6.35)	−9.15 (5.63)
p-value (vs. placebo)	—	0.0230	0.0067	<0.0001
Change in number of tablets/week of sedating H1 antihistamine (diphenhydramine) for itch relief from baseline to Week 12				
Mean (SD)	−1.00 (5.22)	−2.29 (6.85)	−2.94 (7.07)	−4.20 (6.35)
p-value (vs. placebo)	—	0.1356	0.0249	0.0001
Change from baseline in health-related quality of life as measured by the CU-Q2oL [i] at Week 12				
Mean (SD)	−19.7 (19.7)	−19.2 (19.0)	−23.1 (18.6)	−30.5 (19.1)
p-value (vs. placebo)	—	0.9916	0.2891	0.0019

Table 22 Exploratory Endpoints Up to Week 12: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from baseline in EuroQoL−5D Index Score[j] at Week 12				
Mean (SD)	0.09 (0.27)	0.17 (0.25)	0.06 (0.22)	0.20 (0.31)
p-value (vs. placebo)	—	0.1702	0.6730	0.0062
Change from Baseline in MOS Sleep Scale[k], Sleep Disturbance Sub-scale at Week 12				
Mean (SD)	−14.7 (24.9)	−18.0 (24.1)	−14.9 (25.9)	−23.5 (25.7)
p-value (vs. placebo)	—	0.2996	0.7922	0.0088
Change from Baseline in MOS Sleep Scale[k], Snoring Sub-scale at Week 12				
Mean (SD)	0.0 (22.3)	0.0 (25.5)	−4.6 (21.1)	−10.0 (21.2)
p-value (vs. placebo)	—	0.9770	0.2458	0.0106
Change from Baseline in MOS Sleep Scale[k], Short of Breath or Headache Sub-scale at Week 12				
Mean (SD)	0.0 (25.7)	−10.4 (19.8)	−11.6 (27.5)	−10.6 (32.9)
p-value (vs. placebo)	—	0.0365	0.3848	0.1908
Change from Baseline in MOS Sleep Scale[k], Sleep Adequacy Sub-scale at Week 12				
Mean (SD)	8.6 (21.5)	10.1 (30.1)	7.9 (27.3)	13.3 (33.6)
p-value (vs. placebo)	—	0.9297	0.7216	0.1664
Change from Baseline in MOS Sleep Scale[k], Somnolence Sub-scale at Week 12				
Mean (SD)	−8.6 (23.3)	−12.7 (22.9)	−7.7 (22.7)	−12.3 (18.3)
p-value (vs. placebo)	—	0.4721	0.7248	0.2128
Change from Baseline in MOS Sleep Scale[k], Sleep Problems Index I Sub-scale at Week 12				
Mean (SD)	−8.6 (16.9)	−13.6 (17.5)	−10.8 (20.5)	−16.1 (21.7)
p-value (vs. placebo)	—	0.1547	0.5166	0.0138
Change from Baseline in MOS Sleep Scale[k], Sleep Problems Index II Sub-scale at Week 12				
Mean (SD)	−10.7 (18.0)	−14.4 (18.6)	−11.8 (20.6)	−18.1 (21.6)
p-value (vs. placebo)	—	0.2952	0.8194	0.0248
Change from Baseline in MOS Sleep Scale[k], Sleep Quantity Sub-scale at Week 12				
Mean (SD)	0.3 (1.1)	0.6 (1.3)	0.6 (1.8)	0.2 (1.2)
p-value (vs. placebo)	—	0.3159	0.1348	0.7226
Change from Baseline in MOS Sleep Scale[k], Optimal Sleep Sub-scale at Week 12				
Mean (SD)	0.1 (0.6)	0.3 (0.5)	0.0 (0.6)	0.0 (0.6)
p-value (vs. placebo)	—	0.0256	0.5293	0.7046

Table 22 Exploratory Endpoints Up to Week 12: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)

BOCF=baseline-carry-forward; CU-Q2oL=Chronic Urticaria Quality-of-Life Questionnaire; MID=minimally important difference; MOS=Medical Outcomes Study; UAS7=urticaria activity score over 7 days.

[a] Defined as a reduction from baseline in UAS7 score of ≥11 points.

[b] Time to UAS7 MID response is the time (in weeks) from the date of the first dose to the date where UAS7 MID response is first achieved.

[c] The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 12.

[d] Analysis using the observed data were provided on page 385.

[e] Proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12.

[f] The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12.

[g] Derived from patient daily diary data. Measured daily, on a scale of 0 (no interference) to 3 (substantial, woke up often, severe impact on sleep). The weekly sleep interference score is the sum of the daily scores over 7 days (range, 0–21).

[h] Measured daily on a scale of 0 (no interference) to 3 (substantial, severe interference with daily activities). The weekly interference with daily activities score is the sum of the daily scores over 7 days (range, 0–21).

[i] A 23-item CIU specific health-related quality-of-life questionnaire. Total score range, 0–100, with higher scores indicating worse QOL (Baiardini et al. 2005).

[j] The EQ-5D questionnaire is a generic preference-based health-related quality-of-life questionnaire that provides a single index value for health status (EuroQol Group 1990). The EuroQoL-5D Index Score has a range of 0.00–1.00, where a score of 1.00 indicates full health.

[k] The MOS Sleep Scale instrument is comprised of 12 questions that are summarized in nine sub-scales (Spritzer and Hays 2003). For details, see page 1733.

Source: page 387, page 388, page 389, page 391, page 392, page 393, page 394, page 396, page 409, page 410, page 415, page 420.

Table 23 summarizes the results of the analyses of exploratory endpoints up to Week 24 (the end of the treatment period). For the outcomes measuring change from baseline to Week 24 in weekly itch severity score, UAS7, weekly number of hives score, and weekly size of largest hive score, the magnitudes of the mean changes from baseline for each of the omalizumab 75-mg, 150-mg and 300-mg groups are similar to the magnitudes of the changes from baseline to Week 12. However, for these outcomes, the mean changes from baseline to Week 24 for the placebo group are greater than the changes from baseline to Week 12. The result of this is that the treatment effects (difference between the omalizumab and placebo groups) are, in general, smaller at Week 24. For the weekly itch severity score, UAS7, weekly number of hives score, and weekly size of largest hive score, the results of the analyses of changes from baseline to Week 24 were generally more favorable for omalizumab dose groups compared with the placebo group.

The mean changes from baseline to Week 24 for the weekly itch severity score, UAS7, weekly number of hives score, and weekly size of largest hive score observed in the omalizumab 300-mg group were larger in magnitude relative to the mean changes observed for the omalizumab 150-mg and 75-mg groups.

The results of the analysis of the proportion of patients with UAS7 ≤ 6 at Week 24 (exploratory endpoint) were generally consistent with the results from Week 12. At Week 24, 29.9%, 36.3%, and 61.7% of patients achieved UAS7 ≤ 6 in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 25.0% of patients in the placebo group.

The proportions of patients with complete response (UAS7 $= 0$) increased from Week 12 to Week 24 for all treatment groups. At Week 24, 23.4%, 20.0%, and 48.1% of patients achieved a complete response in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively, compared with 12.5% of patients in the placebo group.

For other exploratory endpoints, the results of the analyses were, in general, consistent with the results from the primary and secondary analyses.

Table 23 Exploratory Endpoints Up to the End of Treatment Period (Week 24): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from Baseline in Weekly Itch Severity Score [a] at Week 24 (BOCF)				
Mean (SD)	−5.41 (5.76)	−6.98 (6.42)	−6.47 (6.50)	−9.84 (5.95)
p-value (vs. placebo)	—	0.0687	0.2860	<0.0001
Change from Baseline in UAS7 [b] at Week 24 (BOCF)				
Mean (SD)	−11.73 (12.53)	−14.92 (13.77)	−14.21 (13.33)	−22.11 (12.46)
p-value (vs. placebo)	—	0.1254	0.2126	<0.0001
Change from Baseline in Weekly Number of Hives Score [c] at Week 24 (BOCF)				
Mean (SD)	−6.32 (7.24)	−7.95 (7.73)	−7.75 (7.26)	−12.28 (7.33)
p-value (vs. placebo)	—	0.2094	0.2009	<0.0001
Change from baseline in weekly size of largest hive score [d] at Week 24 (BOCF)				
Mean (SD)	−5.25 (6.69)	−6.33 (7.14)	−6.81 (6.94)	−10.74 (7.00)
p-value (vs. placebo)	—	0.2685	0.1141	<0.0001
Proportion of Patients with UAS7 [b] ≤6 at Week 24				
Mean (SD)	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
p-value (vs. placebo)	—	0.4026	0.1613	<0.0001
Proportion of Patients with a complete response (UAS7=0) [b] at Week 24				
Mean (SD)	10 (12.5%)	18 (23.4%)	16 (20.0%)	39 (48.1%)
p-value (vs. placebo)	—	0.0654	0.2286	<0.0001
Change from baseline in the proportion of itch-free days at Week 24 (BOCF) [e, f]				
Mean (SD)	24.0% (36.5%)	33.7% (43.0%)	31.0% (40.1%)	60.3% (44.9%)
p-value (vs. placebo)	—	0.1348	0.2870	<0.0001
Change from baseline in the proportion of hive-free days at Week 24 (BOCF) [f, g]				
Mean (SD)	26.4% (37.6%)	32.2% (41.7%)	37.2% (44.0%)	65.1% (44.7%)
p-value (vs. placebo)	—	0.3427	0.0944	<0.0001
Change from baseline in the proportion of itch-free and hive-free days at Week 24 (BOCF) [f, h]				
Mean (SD)	21.7% (35.6%)	30.6% (42.3%)	29.9% (40.3%)	59.1% (45.9%)
p-value (vs. placebo)	—	0.1623	0.1949	<0.0001

Table 23 Exploratory Endpoints Up to the End of Treatment Period (Week 24): Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from baseline in weekly sleep interference score[i] at Week 24				
Mean (SD)	−4.89 (5.47)	−6.13 (6.32)	−5.64 (6.54)	−8.49 (6.01)
p-value (vs. placebo)	—	0.2518	0.4587	0.0001
Change from baseline in weekly interference with daily activities score[j] at Week 24				
Mean (SD)	−5.18 (6.01)	−6.61 (6.34)	−6.18 (6.88)	−9.21 (5.96)
p-value (vs. placebo)	—	0.1644	0.2925	<0.0001
Change from Baseline in MOS Sleep Scale[k], Sleep Disturbance Sub-scale at Week 24				
Mean (SD)	−18.5 (25.7)	−18.8 (23.6)	−18.9 (28.7)	−24.1 (25.7)
p-value (vs. placebo)	—	0.7696	0.7012	0.1282
Change from Baseline in MOS Sleep Scale[k], Snoring Sub-scale at Week 24				
Mean (SD)	−0.4 (25.1)	−2.7 (24.5)	−4.7 (28.0)	−8.5 (20.8)
p-value (vs. placebo)	—	0.6992	0.5346	0.1108
Change from Baseline in MOS Sleep Scale[k], Short of Breath or Headache Sub-scale at Week 24				
Mean (SD)	0.8 (21.9)	−6.0 (25.1)	−13.8 (28.8)	−12.8 (28.3)
p-value (vs. placebo)	—	0.4657	0.1386	0.0418
Change from Baseline in MOS Sleep Scale[k], Sleep Adequacy Sub-scale at Week 24				
Mean (SD)	12.0 (25.3)	6.8 (25.7)	13.6 (25.7)	13.5 (34.8)
p-value (vs. placebo)	—	0.1787	0.6519	0.3859
Change from Baseline in MOS Sleep Scale[k], Somnolence Sub-scale at Week 24				
Mean (SD)	−9.2 (21.6)	−11.0 (25.1)	−14.7 (23.1)	−11.7 (21.2)
p-value (vs. placebo)	—	0.7898	0.1482	0.4085
Change from Baseline in MOS Sleep Scale[k], Sleep Problems Index I Sub-scale at Week 24				
Mean (SD)	−12.2 (20.0)	−11.7 (16.2)	−15.9 (22.0)	−16.4 (20.8)
p-value (vs. placebo)	—	0.7114	0.2959	0.2710
Change from Baseline in MOS Sleep Scale[k], Sleep Problems Index II Sub-scale at Week 24				
Mean (SD)	−13.4 (19.5)	−13.0 (17.1)	−16.7 (22.1)	−18.5 (20.3)
p-value (vs. placebo)	—	0.8315	0.4196	0.1951
Change from Baseline in MOS Sleep Scale[k], Sleep Quantity Sub-scale at Week 24				
Mean (SD)	0.4 (1.1)	0.5 (1.5)	0.6 (1.5)	0.2 (1.2)
p-value (vs. placebo)	—	0.7830	0.1288	0.6059

Table 23 Exploratory Endpoints Up to the End of Treatment Period (Week 24): Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Change from Baseline in MOS Sleep Scale[k], Optimal Sleep Sub-scale at Week 24				
Mean (SD)	0.2 (0.6)	0.2 (0.6)	0.2 (0.5)	0.0 (0.6)
p-value (vs. placebo)	—	0.9587	0.4968	0.0527

BOCF=baseline-carry-forward; MOS=Medical Outcomes Study; UAS7=urticaria activity score over 7 days.

[a] Weekly itch severity score is a component of the UAS7. Daily itch severity scores is the average of the morning and evening scores with use of a scale of 0 (none) to 3 (severe). Weekly itch severity score is the sum of the daily scores over 7 days; thus, the weekly score represents pruritus (itch) severity on a scale from 0 (minimum) to 21 (maximum).

[b] The UAS is a composite of recorded score with numeric severity intensity ratings on a scale of 0–3 (0=none to 3=intense/severe) for 1) the number of wheals (hives); and 2) the intensity of the itch, measured twice daily (morning and evening). Daily UAS is the average of morning and evening scores (range, 0–6 points/day) and the UAS7 is the sum of the daily UAS scores over 7 days (range, 0–42).

[c] Number of hives is measured twice daily (morning and evening), on a scale from 0 (none) to 3 (>12 hives per 12 hours). Daily hives score is the average of morning and evening scores, and the weekly hives score is the sum of the daily hives scores over 7 days (range, 0–21).

[d] Measured twice daily, on a scale of 0 (none) to 3 (>2.5 cm). Daily largest hive score is the average of the morning and evening scores, and the weekly largest hive score is the sum of the daily scores over 7 days (range, 0–21).

[e] The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 12.

[f] Analysis using the observed data were provided on page 438.

[g] Proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12.

[h] The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12.

[i] Derived from patient daily diary data. Measured daily, on a scale of 0 (no interference) to 3 (substantial, woke up often, severe impact on sleep). The weekly sleep interference score is the sum of the daily scores over 7 days (range, 0–21).

[j] Measured daily on a scale of 0 (no interference) to 3 (substantial, severe interference with daily activities). The weekly interference with daily activities score is the sum of the daily scores over 7 days (range, 0–21).

[k] The MOS Sleep Scale instrument is comprised of 12 questions that are summarized in nine sub-scales (Spritzer and Hays 2003). For details, see page 1733..

Source: page 440, page 441, page 442, page 443, page 444, page 445, page 446, page 391, page 392, page 448, page 420.

5.4.3 Exploratory Endpoints in the Follow-up Period

Exploratory endpoints in the follow-up period are summarized in Table 24.

The proportion of patients who reached UAS7 ≤6 at Week 24 and maintained their response until Week 40 was 6.5%, 2.5%, and 7.4% in the omalizumab 75-mg, 150-mg,

and 300-mg groups, respectively, compared with 6.3% in the placebo group. Among patients with UAS7 $\leq$6 response at Week 24, the median time to relapse (loss of UAS7 $\leq$6 response) was 3 weeks, 3 weeks, 5 weeks, and 7 weeks for patients in the omalizumab 75-mg, 150-mg, and 300-mg groups and the placebo group, respectively (see page 453). At Week 40, the proportions of patients with UAS7 $\leq$6 were similar for all treatment groups and the proportions of patients with UAS7=0 were similar for all treatment group.

For each of the three omalizumab dose groups, the mean changes from baseline to Week 40 in CU-Q2oL, DLQI and EQ-5D were similar to those for the placebo group.

Table 24 Summary of Exploratory Endpoints in the Follow-up Period (Week 40): Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Proportion of patients with UAS7 [a] ≤6 at Week 40				
Number of patients with UAS7 ≤6 at Week 40 (%)	18 (22.5%)	12 (15.6%)	15 (18.8%)	13 (16.0%)
p-value (vs. placebo)	—	0.2779	0.4409	0.2779
Proportion of Week 24 responders who maintain their response (UAS7 ≤6) to the Week 40 visit				
Number of Week 24 responders [b] (%)	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
Number of patients maintained UAS7 ≤6 at Week 40 (%)	5 (6.3%)	5 (6.5%)	2 (2.5%)	6 (7.4%)
Time to relapse after Week 24 (loss of UAS7 ≤6 response) in Week 24 responders (UAS7 ≤6)				
Number of responders at Week 24 (%)	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
Number of patients Relapsed (UAS7>6) [c] (%)	13 (16.3%)	15 (19.5%)	27 (33.8%)	40 (49.4%)
Time to relapse [d], in weeks	7.0	3.0	3.0	5.0
Proportion of patients with a complete response (UAS=0) [a] at Week 40				
Mean (SD)	11 (13.8%)	7 (9.1%)	9 (11.3%)	8 (9.9%)
p-value (vs. placebo)	—	0.3584	0.5343	0.4266
Change from baseline in CU-Q2oL [e] overall score at Week 40				
Mean (SD)	−25.2 (23.8)	−20.7 (16.7)	−14.2 (19.3)	−17.8 (24.2)
p-value (vs. placebo)	—	0.4676	0.0216	0.0986
Change from baseline in overall DLQI [f] score at Week 40				
Mean (SD)	−7.9 (8.0)	−7.0 (5.8)	−5.2 (6.7)	−4.9 (8.1)
p-value (vs. placebo)	—	0.2001	0.0274	0.0351
Change from baseline in health utility as measured by the EQ-5D [g] at Week 40				
Mean (SD)	0.17 (0.27)	0.15 (0.24)	0.08 (0.22)	0.15 (0.29)
p-value (vs. placebo)	—	0.3281	0.0550	0.9992

Table 24 Summary of Exploratory Endpoints in the Follow-up Period (Week 40): Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)

CU-Q2oL=Chronic Urticaria Quality-of-Life Questionnaire; DLQI=Dermatology Life Quality Index; EQ-5D=EuroQoL-5D; UAS7=urticaria activity score over 7 days.

[a] The UAS is a composite of recorded score with numeric severity intensity ratings on a scale of 0–3 (0=none to 3=intense/severe) for 1) the number of wheals (hives); and 2) the intensity of the itch, measured twice daily (morning and evening). Daily UAS is the average of morning and evening scores (range, 0–6 points/day) and the UAS7 is the sum of the daily UAS scores over 7 days (range, 0–42).

[b] Week 24 responders are defined as patients who achieve an absolute UAS7 $\leq$6 at Week 12.

[c] Week 24 responders who discontinued prior to Week 40 who had not relapsed were censored at the week of their last non-missing UAS7.

[d] Time to relapse is defined as the date of the Week 24 visit to the date where UAS7 >6.

[e] A 23-item CIU specific health-related quality-of-life questionnaire. Total score range, 0–100, with higher scores indicating worse QOL (Baiardini et al. 2005).

[f] The DLQI questionnaire is a 10-item dermatology-specific health-related quality of life measure. Overall DLQI score is calculated by summing the score of each question and has a range of 0–30; the higher the score, the more quality of life is impaired (Finlay and Khan 1994).

[g] The EQ-5D questionnaire is a generic preference-based health-related quality-of-life questionnaire that provides a single index value for health status (EuroQol Group 1990). The EuroQoL-5D Index Score has a range of 0.00–1.00, where a score of 1.00 indicates full health.

Source: page 454, page 455, page 456, page 457, page 394, page 396, page 458, page 409.

5.4.4 Other Exploratory Endpoints

A summary of action(s) taken in response to angioedema based on patient daily diary data is presented on page 459. The summary was based on observed data; no imputation was done for patients with missing data.

For patients in all treatment groups over the 24-week treatment period, the proportion of patients who had angioedema decreased. By Week 1 the proportion of patients in the omalizumab 300-mg group who reported angioedema had decreased to 27.5% and continued to decrease to 12.5% at Week 12 and approximately 8% by Week 24 (see page 459 and Table 25). A similar pattern was observed in the other treatment groups and the placebo group where the proportion of patients who experienced angioedema at least 1 day during the week decreased by Week 1 and continued to decrease over time to Week 24. After Week 24, the proportion of patients who had angioedema in the placebo group, omalizumab 150-mg, and 300-mg groups ranged between 10% and 20% to Week 40, while the proportion of patients who had angioedema in the omalizumab 75-mg group ranged from 20% to 38% (see page 459). Among patients who reported angioedema for a given week, the average number of days patients had angioedema remained fairly constant over time for each treatment

group after Week 24. Angioedema management at baseline and throughout the course of the treatment period generally consisted of low-intensity interventions, if any: most patients reported doing nothing or taking medication and some patients reported having called or visited their health care provider. In the placebo group, one patient was hospitalized and two patients visited an emergency department for treatment of their angioedema. Two patients in the omalizumab 75-mg group visited an emergency department for treatment of their angioedema. One patient in the omalizumab 300-mg group was hospitalized.

Table 25 Summary of Angioedema Occurrences at Baseline and Week 24: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Baseline				
n	80	77	80	81
Number of patients who had angioedema [a]	44 (55.0%)	35 (45.5%)	38 (47.5%)	34 (42.0%)
Mean (SD) number of days a patient had angioedema (all patients)	1.45 (1.83)	1.71 (2.43)	1.76 (2.31)	1.15 (1.77)
Week 12				
n	64	65	62	72
Number of patients who had angioedema [a]	17 (26.6%)	14 (21.5%)	10 (16.1%)	9 (12.5%)
Mean (SD) number of days a patient had angioedema (all patients)	0.76 (1.58)	0.88 (2.01)	0.58 (1.64)	0.33 (1.01)
Week 24				
n	54	62	55	67
Number of patients who had angioedema [a]	6 (11.1%)	17 (27.4%)	5 (9.1%)	5 (7.5%)
Mean (SD) number of days a patient had angioedema (all patients)	0.27 (0.86)	1.16 (2.22)	0.24 (0.90)	0.21 (1.00)

SD=standard deviation.

[a] Percents of patients who had angioedema is based on n (the number of patients who had nonmissing data).

Source: page 459.

A summary of health care visits for CIU (calling a doctor, nurse, or nurse practitioner) based on patient daily diary data by week is summarized on page 485. The proportions of patients reporting calls to a healthcare provider for CIU during the week prior to their first study treatment (baseline) ranged from 1.3% in the placebo group to 7.5% in the

omalizumab 150-mg group. By Week 24, the proportions of patients reporting calls to a healthcare provider for CIU ranged from 0% in the placebo group to 2.6% in the omalizumab 75-mg group (see page 485).

The correlations between the change from baseline in basophil high-affinity IgE receptor density and the change from baseline in weekly itch severity score at Weeks 12, 24 and 40 are summarized on page 496, page 499, page 500, and page 501. A decrease of the basophil high-affinity IgE receptor density measured in molecules of equivalent, soluble fluorochrome units (MESF) was observed at Week 12 for patients in the omalizumab groups (all doses). At Week 12, the median relative change from baseline in basophil high-affinity IgE receptor density was −51.1%, −70.0%, and −81.4% in the omalizumab 75-mg 150-mg, and 300-mg groups, respectively, compared with 17.3% in the placebo group (see page 496). The correlation between the relative change in basophil high-affinity IgE receptor density and the primary endpoint (change from baseline in weekly itch severity score at Week 12) in terms of Spearman's correlation coefficient ranged from 0.0498 (omalizumab 75-mg group) to 0.1982 (omalizumab 300-mg group). At Week 24, the median relative change from baseline in basophil high affinity IgE receptor density was −42.2%, −64.5%, and −81.1% in the omalizumab 75-mg 150-mg, and 300-mg groups, respectively, compared with 36.4% in the placebo group. The correlation between the relative change in basophil high-affinity IgE receptor density and the primary endpoint (change from baseline in weekly itch severity score at Week 24) in terms of Spearman's correlation coefficient ranged from −0.0754 (omalizumab 300-mg group) to 0.3461 (omalizumab 150-mg group). At Week 40, the median relative change from baseline in basophil high affinity IgE receptor density was an increase of 25.9%, 29.4%, and 19.8% in the omalizumab 75-mg 150-mg, and 300-mg groups, respectively, compared to an increase of 29.2% in the placebo group. The median percent change from baseline in basophil high-affinity IgE receptor density (MESF) by study visit is presented on page 502.

5.5 STATISTICAL AND ANALYTICAL ISSUES

5.5.1 Adjustments for Covariates

The analyses of the primary efficacy endpoint included adjustment for baseline weekly itch severity score (<13, ≥13) and weight (<80 kg, ≥80 kg). The randomization scheme was a hierarchical dynamic randomization method stratified by baseline weekly itch severity score (<13, ≥13), weight (<80 kg, ≥80 kg), and study site. Because of the large number (53) of study sites, the study site was last in the order of stratification factors in the hierarchical dynamic randomization algorithm. Many sites enrolled only 2 to 3 patients and consequently did not enroll at least 1 patient in each of the treatment groups. Therefore, study site was not included as a covariate in the analysis in order to avoid substantially increasing the variation in estimated treatment effects. The analyses of the secondary efficacy endpoints and exploratory efficacy endpoints included adjustment for the baseline score strata of the respective endpoint (<median, ≥median)

in addition to baseline weight (< 80 kg, ≥ 80 kg). The statistical methods used to adjust for the baseline strata and covariates are provided in the SAP on page 1658.

5.5.2 Handling of Dropouts or Missing Data

Methods for handling missing data for efficacy endpoints are described in Sections 4.4 and 4.7 of the SAP on page 1671 and page 1689, respectively.

5.5.2.1 Patient Diary Completion

The majority of efficacy endpoints in this study, including the primary endpoint, were based on data recorded on the patient daily eDiary. Patient eDiary compliance was examined and is summarized in Table 26. The mean proportion of days a patient recorded at least one diary entry was > 96% for each treatment group during the first 12 weeks of the treatment period and >95% during the entire 24-week treatment period (efficacy endpoints required at least a once-daily response to have daily scores calculated). The mean proportion of days with both diary entries completed was ≥ 88% for each treatment group during the first 12 weeks of the treatment period and ≥ 86% during the entire 24-week treatment period. The mean proportion of days patients reported at least one diary entry was > 91% for each treatment group during the follow-up period.

Table 26 Daily Diary Compliance Rate: Modified Intent-to-Treat Population

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
First Half of the Treatment Period (Day 1–Week 12)				
Proportion of days with morning entry				
n	80	77	80	81
Mean (SD)	93.7% (10.0%)	92.7% (15.5%)	94.9% (9.2%)	95.1% (7.4%)
Median	97.0%	97.6%	97.6%	97.6%
Range	26.2%–100.0%	4.8%–100.0%	34.5%–100.0%	69.0%–100.0%
Proportion of days with evening entry				
n	80	77	80	81
Mean (SD)	93.5% (10.2%)	91.8% (15.9%)	94.8% (8.4%)	94.6% (9.0%)
Median	96.4%	97.6%	97.6%	97.6%
Range	25.0%–100.0%	2.4%–100.0%	36.9%–100.0%	47.6%–100.0%
Proportion of days with at least one (morning or evening) daily entry				
n	80	77	80	81
Mean (SD)	97.8% (8.8%)	96.5% (14.5%)	98.8% (5.0%)	98.9% (3.7%)
Median	100.0%	100.0%	100.0%	100.0%
Range	31.0%–100.0%	4.8%–100.0%	58.3%–100.0%	78.6%–100.0%
>85%	77 (96.3%)	74 (96.1%)	79 (98.8%)	79 (97.5%)
Proportion of days with both morning and evening daily entry				
n	80	77	80	81
Mean (SD)	89.4% (11.9%)	88.0% (17.8%)	90.9% (12.6%)	90.8% (11.8%)
Median	91.7%	95.2%	95.0%	96.4%
Range	20.2%–100.0%	2.4%–100.0%	13.1%–100.0%	39.3%–100.0%
Treatment Period (Day 1–Week 24)				
Proportion of days with morning entry				
n	80	77	80	81
Mean (SD)	92.7% (9.7%)	91.2% (15.9%)	94.1% (9.0%)	94.1% (9.4%)
Median	96.4%	97.6%	97.4%	97.6%
Range	37.8%–100.0%	11.4%–100.0%	50.3%–100.0%	56.4%–100.0%
Proportion of days with evening entry				
n	80	77	80	81
Mean (SD)	92.4% (10.0%)	90.6% (15.8%)	93.6% (8.4%)	93.2% (10.1%)
Median	94.6%	95.8%	96.5%	97.0%
Range	30.8%–100.0%	9.0%–100.0%	51.5%–100.0%	39.0%–100.0%

Table 26 Daily Diary Compliance Rate: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Treatment Period (Day 1–Week 24) (cont.)				
Proportion of days with at least one (morning or evening) daily entry				
n	80	77	80	81
Mean (SD)	97.6% (7.5%)	95.8% (14.2%)	98.4% (4.7%)	98.2% (5.0%)
Median	100.0%	100.0%	100.0%	100.0%
Range	47.7%–100.0%	13.8%–100.0%	65.9%–100.0%	69.8%–100.0%
>85%	76 (95.0%)	72 (93.5%)	78 (97.5%)	78 (96.3%)
Proportion of days with both morning and evening daily entry				
n	80	77	80	81
Mean (SD)	87.5% (12.4%)	86.0% (18.5%)	89.3% (12.6%)	89.1% (14.1%)
Median	90.4%	93.9%	92.4%	95.2%
Range	20.9%–100.0%	6.6%–100.0%	35.9%–100.0%	25.6%–100.0%
Follow-up Period (Week 24–Week 40)				
Proportion of days with morning entry				
n	77	73	80	78
Mean (SD)	85.7% (19.7%)	85.7% (16.4%)	87.3% (15.1%)	88.8% (17.5%)
Median	92.0%	92.0%	92.9%	95.5%
Range	0.8%–100.0%	27.3%–100.0%	33.3%–100.0%	10.9%–100.0%
Proportion of days with evening entry				
n	71	73	80	77
Mean (SD)	84.3% (17.2%)	85.6% (15.9%)	85.2% (16.0%)	88.7% (14.2%)
Median	89.1%	91.2%	91.4%	93.3%
Range	2.6%–99.2%	18.2%–99.1%	8.3%–99.1%	8.7%–100.0%
Proportion of days with at least one (morning or evening) daily entry				
n	77	73	80	78
Mean (SD)	91.9% (18.2%)	93.1% (12.7%)	94.3% (10.2%)	94.0% (15.2%)
Median	97.7%	98.2%	98.2%	99.1%
Range	0.8%–100.0%	36.4%–100.0%	33.3%–100.0%	11.1%–100.0%
>85%	70 (87.5%)	62 (80.5%)	69 (86.3%)	69 (85.2%)

Table 26 Daily Diary Compliance Rate: Modified Intent-to-Treat Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=77)	Omalizumab 150 mg (n=80)	Omalizumab 300 mg (n=81)
Follow-up Period (Week 24–Week 40) (cont.)				
Proportion of days with both morning and evening daily entry				
n	71	73	80	77
Mean (SD)	77.6% (20.6%)	78.2% (20.0%)	78.2% (20.5%)	83.5% (17.9%)
Median	83.3%	85.0%	85.8%	89.1%
Range	2.6%–99.1%	9.1%–99.1%	8.3%–99.1%	5.1%–99.1%

Note: Proportions are based on number of nonmissing daily diary entries for a patient within the total number of days during a period that the patient was active.

Source: page 503

5.5.2.2 Patients with Data Imputed by Baseline Score in the Primary and Secondary Endpoints

Following the SAP, the weekly scores at Week 12 were imputed by the baseline score (BOCF) for patients who:

1. Discontinued prematurely from study treatment prior to Week 12, or
2. Received excluded therapy prior to Week 12 (listed in Section 4.4.2 of Study Q4881g Protocol on page 1443), or
3. Had fewer than 4 days of nonmissing diary entries during Week 12

The imputed Week 12 scores were used for the analyses of the primary endpoint and the following secondary endpoints:

- Change from baseline in UAS7 at Week 12
- Change from baseline in weekly number of hives score at Week 12
- Change from baseline in weekly size of the largest hive score at Week 12

These criteria for imputation were also used to classify patients as nonresponders when the Week 12 data were not available for the following two secondary endpoints:

- Proportion of patients with UAS7 $\leq$ 6 at Week 12
- Proportion of weekly itch severity score MID Responders at Week 12

It should be noted that the design of the eDiary device did not allow for partial completion of the diary entry. For example, for the morning entry a patient had to complete all four questions (itch severity, number of hives, size of largest hive, and sleep interference) in the diary in order to submit the entry. That is, for a given entry, responses were either all missing or all nonmissing. Hence, the rates of missingness for the above endpoints are the same.

Table 27 summarizes the number of patients who had their scores imputed using their baseline score for the analysis of the primary endpoint and the secondary endpoints listed above at Week 12. The placebo and omalizumab 150-mg groups had the highest proportions (20.0%) of patients with Week 12 scores imputed using baseline scores, followed by the omalizumab 75-mg group (14.3%) and the omalizumab 300-mg group (9.9%).

Table 27 Number of Patients Whose Week 12 Diary Scores were Imputed by Baseline Scores: Modified Intent-to-Treat Population

Genentech, Inc. Study q4881g
Xolair (Omalizumab) Xolair in Refractory Chronic Idiopathic Urticaria (CIU)

Table 14.2/51
Patients with Week 12 Diary Scores Imputed by Baseline Scores
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Total	16 (20.0%)	11 (14.3%)	16 (20.0%)	8 (9.9%)
Discontinued from treatment	14 (17.5%)	7 (9.1%)	11 (13.8%)	5 (6.2%)
Took Excluded Medication but did not discontinue from treatment	1 (1.3%)	2 (2.6%)	3 (3.8%)	1 (1.2%)
Had less than 4 days of diary records at Wk12 but did not discontinue from the treatment or took excluded meds	1 (1.3%)	2 (2.6%)	2 (2.5%)	2 (2.5%)

*Discontinued from treatment prior to week 12.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_w12_imp)
Database (CLOSED) Datasets (pat pateff)
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5.5.2.3 Additional Approaches to Handle Missing Data

To assess the robustness of the results, sensitivity analyses on the primary endpoint were performed using different approaches to handle missing data. For details, see Section 5.2.

5.5.3 Interim Analyses and Data Monitoring

An iDMC was established to monitor the safety and study conduct and met at regular intervals (approximately every 6 months) to review unblinded data summaries prepared by an external data coordinating center. The roles and responsibilities of the iDMC and the details of the analysis plan and data included at each interim safety review by the iDMC are described in the iDMC Charter (see page 1809). The iDMC evaluated only the baseline, safety, disposition, and eligibility data during the scheduled interim safety analyses. No interim analyses were performed for the efficacy data. There were no recommendations or changes to the study conduct as a result of the iDMC's review.

5.5.4 Multicenter Studies

The number of patients enrolled by each investigator is summarized on page 228. Efficacy analyses were not performed by study center.

5.5.5 Multiple Comparison/Multiplicity

Details of the type I error control plan for the primary and secondary efficacy endpoints are provided in the SAP (see page 1658). With respect to the primary endpoint, the differences in treatment effect between each of the omalizumab groups and the placebo group were statistically significant ($p < 0.05$), and therefore the hierarchical analyses of the secondary endpoints were conducted independently within each dose level, in accordance with the plan outlined in the SAP.

5.5.6 Use of an Efficacy or "As Observed" Subset of Patients

Descriptive summaries based on observed data, with no imputation for missing data, were performed to examine the robustness of the primary analysis for the primary endpoint and three secondary endpoints: change from baseline in UAS7 at Week 12, change from baseline in weekly number of hives score at Week 12, and change from baseline in weekly size of largest hive score (see page 510, page 517, page 518, page 525, page 526, page 533, page 534). The means and mean changes from baseline to Week 12 based on observed data were generally consistent with the results using the BOCF imputation method for missing Week 12 scores.

The primary analysis of the secondary endpoint, change from baseline in overall DLQI score at Week 12, was based on observed data. A sensitivity analysis was performed where missing Week 12 scores were imputed using the BOCF method (see page 541). It was noted that, for this endpoint, all three omalizumab groups showed a larger treatment effect when imputation was used than in the primary analysis based on observed data (see page 314). Based on the analysis of the change from baseline in

overall DLQI score at Week 12 with missing scores imputed using the BOCF method, the difference between the omalizumab 150-mg group and the placebo group was statistically significant in favor of omalizumab ($p=0.0430$) in contrast to the results based on observed data where the mean change from baseline at Week 12 was not statistically significant compared with patients in the placebo group ($p=0.2286$).

5.5.7 Dynamic Randomization

The study used a hierarchical dynamic randomization scheme to obtain an approximately 1:1:1:1 ratio across the four treatment groups. The levels in this hierarchy were overall study treatment balance, treatment balance within the baseline weekly itch severity score strata (<13, ≥ 13), treatment balance within the body weight strata (<80 kg, ≥ 80 kg), and balance within each study center.

Re-randomization tests for the primary and secondary efficacy endpoints were performed using computer simulations. The simulation study re-randomized the 319 patients 10,000 times with use of the same randomization stratification factors observed in the study, (i.e., baseline weekly itch severity score strata [<13, ≥ 13], body weight strata [<80 kg, ≥ 80 kg], and study center). The analyses of the primary and secondary efficacy endpoint were conducted for each of the re-randomized patient cohorts. The test statistics generated by the simulation cohorts were used to generate a "re-randomization distribution" for each of the endpoints. A p-value was then computed as the proportion of simulated test statistics that exceeded the observed test statistic for each endpoint. The p-values obtained by the re-randomization simulations and the model-based p-values are presented in Table 28. The re-randomization p-values were similar to the model-based p-values for all endpoints, which demonstrates the robustness of the model-based results.

Table 28 Re-randomization Test Results

	Omalizumab 75 mg		Omalizumab 150 mg		Omalizumab 300 mg	
	Model-Based p-value	Re-randomization simulation p-value	Model-Based p-value	Re-randomization simulation p-value	Model-Based p-value	Re-randomization simulation p-value
Change from baseline in Weekly itch severity score at Week 12	0.0010	0.0014	0.0012	0.0014	<0.0001	<0.0001
Change from baseline in UAS7 at Week 12	0.0035	0.0035	0.0008	0.0009	<0.0001	<0.0001
Change from baseline in weekly number of hives score at Week 12	0.0149	0.0146	0.0017	0.0024	<0.0001	<0.0001
Time to MID response in weekly itch severity score by Week 12	0.0879	0.0794	0.0301	0.0244	<0.0001	<0.0001
Proportion of patients with UAS7 ≤ 6 at Week 12	0.0148	0.0166	<0.0001	0.0001	<0.0001	<0.0001
Proportion of weekly itch severity score MID responders at Week 12	0.0118	0.0124	0.0226	0.0231	<0.0001	<0.0001
Change from baseline in weekly size of largest hive score at Week 12	0.0124	0.0119	0.0012	0.0012	<0.0001	<0.0001
Change from baseline in health-related quality of life as measured by the DLQI at Week 12	0.7956	0.7925	0.2286	0.2151	<0.0001	<0.0001
Proportion of angioedema-free days from Week 4 to Week 12 of therapy	0.4867	0.4968	0.1747	0.1803	<0.0001	0.0001
Proportion of Complete Responders (UAS7 = 0) at Week 12	0.4580	0.4660	0.2087	0.2114	<0.0001	<0.0001

6. PHARMACOKINETIC AND PHARMACODYNAMIC RESULTS

6.1 OMALIZUMAB AND IGE CONCENTRATIONS

PK and PD results are summarized on page 542, page 544, page 546, page 548, page 550, and page 1010. The PK and PD analyses were conducted using the PK-evaluable population, and are based on the treatment actually received. For patients who received open-label omalizumab during the follow-up period, omalizumab and IgE concentration data collected on or after the date of open-label omalizumab treatment were excluded from the analyses. For details on the assay and sample analysis methods see the bioanalytical reports for serum total omalizumab levels on page 2664 total IgE determination on page 2480 and free IgE levels on page 2582.

Blood samples were collected to determine serum concentrations of omalizumab, free IgE, and total IgE at Day 1 (predose), Week 12, Week 24 (end of treatment period) and Week 40 (end of follow-up period).

Following SC injections of omalizumab 75 mg, 150 mg, and 300 mg every 4 weeks, the mean (±SD) observed serum omalizumab concentrations were 7.41 (±4.55) μg/mL, 13.3 (±7.3) μg/mL, and 30.6 (±15.6) μg/mL at Week 12; and 7.63 (±4.2) μg/mL, 14.0 (±8.79) μg/mL, and 30.9 (±15.3) μg/mL at Week 24 for the three dose groups, respectively (see Table 29). The mean concentrations at Week 12 and Week 24 were proportional to the dose level. The concentrations at Week 24 were similar to those at Week 12 in patients for each dose group, suggesting that steady state was approached by Week 12. The mean observed serum omalizumab concentrations at Week 40 (end of follow-up period) were substantially lower than those observed during the treatment period.

In the placebo group, 2 patients (Patients [redacted] and [redacted] had omalizumab concentrations (20.0 μg/mL at Week 12 in Patient [redacted] and 19.6 μg/mL at Week 40 in Patient [redacted]; see page 1010) comparable to concentrations observed in patients who received omalizumab. Possible reasons for these omalizumab concentration values were examined, but could not be attributed to known omalizumab exposure prior to or during the study, mislabeling of samples or assay issues. The concentrations at baseline in both patients were below the lower limit of quantification (LLOQ). Hence, the omalizumab concentration values in these two samples were considered to be aberrant.

Table 29 Mean (Standard Deviation) Serum Omalizumab, Free IgE and Total IgE Concentrations by Dose Group and Timepoint: Pharmacokinetic-Evaluable Population

Analyte	Visit	Placebo	Omalizumab 75 mg	Omalizumab 150 mg	Omalizumab 300 mg
Omalizumab (μg/mL) Mean (SD)	Day1 (Predose)[a]	0.00801 (0.0568)	0.0297 (0.13)	0.00742 (0.0243)	0.00458 (0.026)
	Week 12	NR (NR)	7.41 (4.55)	13.3 (7.30)	30.6 (15.6)
	Week 24	NR (NR)	7.63 (4.20)	14.0 (8.79)	30.9 (15.3)
	Week 40	NR (NR)	0.346 (0.411)	1.96 (10.2)	2.01 (2.72)
Free IgE (IU/mL) Mean (SD)	Day1 (Predose)	NR (NR)	NR (NR)	NR (NR)	NR (NR)
	Week 12	NR (NR)	23.3 (21.6)	17.7 (18.2)	9.01 (10.2)
	Week 24	NR (NR)	24.8 (21.8)	19.3 (20.2)	8.11 (9.52)
	Week 40	NR (NR)	NR (NR)	NR (NR)	NR (NR)
Total IgE (IU/mL) Mean (SD)	Day1 (Predose)	161 (215)	203 (346)	216 (590)	153 (285)
	Week 12	166 (237)	444 (667)	461 (683)	508 (693)
	Week 24	179 (393)	464 (662)	533 (849)	470 (664)
	Week 40	153 (258)	209 (385)	262 (684)	206 (269)

LLOQ = lower limit of quantification; NR = non reportable; ULOQ = upper limit of quantification.

Notes: A result is NR when > 1/3 of the values are lower than reportable or > 1/3 of the values are greater than reportable. LLOQ: 0.028 μg/mL for omalizumab, 0.83 IU/mL for free IgE, 2 IU/mL for total IgE. ULOQ: none for omalizumab, 62.0 IU/mL for free IgE, 5000 IU/mL for total IgE.

[a] Values less than reportable on Day 1 (predose) were set to 0.

Sources: page 542; page 548; page 544.

The measured serum total IgE levels at baseline were used as the baseline for serum free IgE, since omalizumab-IgE complexes would not have formed prior to study drug administration. The mean (±SD) baseline IgE concentrations were 161 (± 215) IU/mL, 203 (±346) IU/mL, 216 (±590) IU/mL, and 153 (±285) IU/mL for patients in the placebo, omalizumab 75-mg, 150-mg, and 300-mg groups, respectively (see Table 29). After treatment with omalizumab, the free IgE level decreased dose dependently. The mean (±SD) observed free IgE concentrations at Week 12 were 23.3 (±21.6) IU/mL, 17.7 (±18.2) IU/mL, and 9.01 (±10.2) IU/mL for patients in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively. The free IgE level remained stable from Week 12 to Week 24. During the follow-up period, the free IgE levels approached those observed at baseline, and by Week 40, more than one-third of the samples were above the upper limit of quantification (62 IU/mL). For patients in the placebo group, the free IgE levels were above the upper limit of quantification in more than one-third of the samples at all timepoints (see page 548).

Following omalizumab treatment, the mean (±SD) observed serum total IgE concentrations for the three dose groups increased by 2- to 3-fold, from: 203 (±346) IU/mL, 216 (±590) IU/mL, and 153 (±285) IU/mL at baseline to 444 (±667) IU/mL, 461 (±683) IU/mL, and 508 (±693) IU/mL at Week 12 for patients in the omalizumab 75-mg, 150-mg, and 300-mg groups, respectively (see Table 29). The total IgE level remained stable from Week 12 to 24. At the end of the follow-up period (Week 40), the serum total IgE levels returned close to baseline. In the placebo group, the mean (±SD) total IgE levels were similar at baseline, Week 12, Week 24 and Week 40.

In summary, following SC administration of omalizumab 75 mg, 150 mg, or 300 mg every 4 weeks, mean serum omalizumab concentrations at Week 12 and Week 24 increased proportionally with dose level. The concentrations at Week 24 were similar to those at Week 12 in patients for each dose group, suggesting that steady state was approached by Week 12. Mean serum free IgE levels were suppressed dose dependently from baseline to Week 12, remained stable from Week 12 to Week 24, and recovered toward baseline by the end of the follow-up period. Mean serum total IgE levels increased 2- to 3-fold from baseline to Week 12, remained stable from Week 12 to Week 24, and returned close to baseline by the end of the follow-up period.

Population PK-PD analysis of the omalizumab, free IgE and total IgE concentration data are performed and reported separately. Additionally, the relationships between post-treatment free IgE or omalizumab concentrations with efficacy responses are assessed and reported separately.

7. SAFETY RESULTS

7.1 OVERVIEW OF SAFETY

The AE summaries in this section are based on treatment-emergent AEs unless specified otherwise. A treatment-emergent AE was defined as any AE reported at the time of or after the first dose of study drug. The safety results of this study indicate that omalizumab was well tolerated, and no new safety concerns aside from those already known with omalizumab use in patients with moderate to severe asthma were identified, as summarized below:

- During the treatment period, the proportions of patients who experienced at least one treatment-emergent AE was higher in the omalizumab group than the placebo group: 58.6% in the omalizumab 75-mg group, 69.0% in the omalizumab 150-mg group, 56.8% in the omalizumab 300-mg group, and 51.3% in the placebo group.
    - The event types that account for the higher AE rate in the omalizumab groups were headaches (nervous system disorders system organ class [SOC]), arthralgia (musculoskeletal and connective tissue disorders SOC), and injection-site reactions (general disorders and administration site conditions SOC), which are events that are known to occur with omalizumab use in patients with moderate to severe asthma.

- The proportions of patients experiencing at least one AE suspected to be caused by study drug increased with increasing omalizumab dose: 6 patients (8.6%) in the omalizumab 75-mg group, 9 patients (10.3%) in the omalizumab 150-mg group, 14 patients (17.3%) in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group. The majority of these AEs were mild or moderate in intensity.
- During the treatment period, 21 patients (6.6%) experienced a severe AE: 5 patients (7.1%) in the omalizumab 75-mg group, 5 patients (5.7%) in the omalizumab 150-mg group, 3 patients (3.7%) in the omalizumab 300-mg group, and 8 patients (10.0%) in the placebo group.
- No deaths occurred during the study.
- During the treatment period, 9 patients (2.8%) experienced an SAE: 2 patients (2.9%) in the omalizumab 75-mg group, 3 patients (3.4%) in the omalizumab 150-mg group, no patients in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group. None of the reported SAEs were assessed by the investigator to be related to study drug.
- During the follow-up period, 5 patients (1.6%) experienced at least one SAE: no patients in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 1 patient (1.3%) in the placebo group. None of the reported SAEs were assessed by the investigator to be related to study drug.
- A total of 15 patients (4.7%) experienced a treatment-emergent AE that led to withdrawal of study drug: 2 patients (2.9%) in the omalizumab 75-mg group, 4 patients (4.6%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 7 patients (8.8%) in the placebo group.
- Five patients (1.6%) withdrew from the study because of a treatment-emergent AE: 1 patient (1.3%) in the omalizumab 75-mg group, 1 patient (1.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group.
- Treatment-emergent AESIs for omalizumab treatment were identified by an ascertainment process based on a search of MedDRA preferred terms, SMQs searches, or modified SMQs searches. In addition to SMQ searches, an ascertainment algorithm of preferred terms was used to select candidate patients with possible anaphylaxis and serum sickness syndrome for clinical adjudication of these events of special interest (see algorithm in Section 3.8.5.2 and summary of results in Table 39). Suspected cases of anaphylaxis identified by the Sponsor were sent for blinded, external adjudication.
    - No events were reported in this study for the following AESI: Churg-Strauss syndrome, malignancy, serum sickness syndrome, and liver-related investigations, signs and symptoms.
        - Three patients were identified by the Sponsor as suspected cases of anaphylaxis and submitted for blinded, external adjudication. Results of the external adjudication are summarized below. Details are in Section 7.9.1.

- Patient [redacted] (omalizumab 150 mg): adverse event was assessed as not anaphylaxis
- Patient [redacted] (omalizumab 300 mg): adverse event was assessed as anaphylaxis and was considered an allergic drug reaction related to dipyrone
- Patient [redacted] (omalizumab 75 mg): adverse event originally reported as an exacerbation of urticaria was assessed as anaphylaxis due to concomitant gastrointestinal symptoms and not attributed to omalizumab.

o Thirty-one patients (9.7%) experienced an event considered a possible hypersensitivity reaction: 3 patients (4.3%) in the omalizumab 75-mg group, 9 patients (10.3%) in the omalizumab 150-mg group, 9 patients (11.1%) in the omalizumab 300-mg group, and 10 patients (12.5%) in the placebo group. Five events were reported as severe: 2 patients (Patients [redacted] and [redacted] in the omalizumab 150-mg group; 2 patients (Patients [redacted] and [redacted]) in the omalizumab 300-mg group; and 1 patient (Patient [redacted] in the placebo group (discontinued from study drug). All events were assessed by the investigators as not serious (except for Patient [redacted] and not study drug related (except for Patients [redacted] and [redacted].

o Two patients (0.6%) experienced an event considered a possible injection-site reaction (defined using SMQ extravasation events [injection, infusion, and implants] search): Patient [redacted] in the omalizumab 75-mg group and Patient [redacted] in the placebo group. The investigators assessed the event (injection-site reaction [swelling]) in Patient [redacted] as not related to the study drug, and the event (injection site pain) in Patient [redacted] as related to the study drug.

o One patient ([redacted]) in the placebo group experienced an event of cervical dysplasia; however, after receiving the pathology report for this patient post-database lock, it was determined that this patient experienced cervical adenocarcinoma in situ. For further detail see Section 7.9.5.

o No core cases of serum sickness were reported. After elimination of cases that did not meet the temporal criteria associating events in Categories A and B, and of cases in which one qualifying event was CIU, no cases were considered likely to be serum sickness syndrome (see Section 7.9.6 for descriptions and reasons for exclusion).

o Fourteen patients (4.4%) experienced an event considered possible skin rash: 5 (7.1%) patients in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 3 patients (3.7%) in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group. All events were assessed by the investigator as not serious and not study drug related except for Patients [redacted] (omalizumab 150-mg group) and [redacted] (omalizumab 300-mg group) who were assessed by the investigator as not serious and related to study drug.

- One patient ([redacted]) in the omalizumab 300-mg group experienced an event considered possible thrombocytopenia. For further detail see Section 7.9.8.
- Ten patients (3.1%) experienced a possible bleeding related event: 2 patients (2.9%) in the omalizumab 75-mg group, 1 patient (1.1%) in the omalizumab 150-mg group, 5 patients (6.2%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group. All bleeding events were assessed as mild or moderate in intensity. All of the bleeding related events were assessed not related to the study drug except for one (Patient [redacted], omalizumab 300-mg group).
- Five patients (1.6%) experienced an event considered a possible hematopoietic cytopenia: 2 patients (2.3%) in the omalizumab 150-mg group, and 3 patients (3.7%) in the omalizumab 300-mg group. One event of thrombocytopenia in Patient [redacted] (omalizumab 300 mg) was assessed by the investigators as related to study drug.
- As part of the SMQ search for ATEs, a broad search for cardiac ischaemic events identified 1 patient ([redacted]) in the omalizumab 150-mg group. The investigators assessed the event as serious and not related to the study drug and related to concurrent illness
- Thirteen patients (4.1%) experienced a possible asthma/bronchospasm event: 2 patients (2.9%) in the omalizumab 75-mg group, 5 patients (5.7%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group. Eleven of the 13 patients identified had a history of asthma/bronchospasm at baseline except Patient [redacted] (omalizumab 75-mg group) and Patient [redacted] (omalizumab 150-mg group).

- For all hematology lab parameters, no notable changes or major differences across treatment groups were observed in the values assessed.

Table 30 summarizes the key safety findings.

Table 30 Overview of Patients with Adverse Events: Safety-Evaluable Population

	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any AE during treatment period	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
AE suspected to be caused by study drug	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
Severe AE during treatment period	8 (10.0%)	5 (7.1%)	5 (5.7%)	3 (3.7%)	21 (6.6%)
Deaths	0	0	0	0	0
SAEs during treatment period	4 (5.0%)	2 (2.9%)	3 (3.4%)	(0.0%)	9 (2.8%)
SAEs during follow-up	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
Withdrawal from study due to AE	2 (2.5%)	0	2 (2.3%)	1 (.2%)	5 (1.6%)
AE leading to withdrawal from treatment	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)

AE=adverse event; SAE=serious adverse event.

Source: page 552, page 660, page 569, page 589, page 591, page 592, page 595.

For a summary of patients with AESI reported see Table 39.

Narratives are provided for patients who experienced SAEs, AEs that led to withdrawal from study treatment or from the study, and pregnancies and all possible cases of anaphylaxis (see page 187). There were no deaths reported in this study.

7.2 EXTENT OF EXPOSURE TO STUDY TREATMENT

Omalizumab exposure is summarized in Table 31. The mean duration of omalizumab exposure for the three doses of 75 mg, 150 mg, and 300 mg was about 22 weeks, with a range of 20.4–22.2 weeks. The median number of doses for each of the three omalizumab treatment groups and the placebo group was 6.0. See Section 4.2 for the reasons for treatment discontinuation.

Table 31 Extent of Exposure to Study Drug: Safety-Evaluable Population

	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Duration of exposure (weeks)					
n	80	70	87	81	318
Mean (SD)	20.4 (6.9)	22.0 (5.3)	21.8 (5.1)	22.2 (5.2)	21.6 (5.7)
Median	24.0	24.0	24.0	24.0	24.0
Range	4–25	4–25	4–26	4–25	4–26
Duration of exposure (patients)					
n	80	70	87	81	318
1–4 weeks	7 (8.8%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	15 (4.7%)
5–8 weeks	6 (7.5%)	4 (5.7%)	6 (6.9%)	0	16 (5.0%)
9–12 weeks	2 (2.5%)	1 (1.4%)	3 (3.4%)	3 (3.7%)	9 (2.8%)
13–16 weeks	2 (2.5%)	3 (4.3%)	3 (3.4%)	0	8 (2.5%)
17–20 weeks	1 (1.3%)	0	3 (3.4%)	0	4 (1.3%)
21–24 weeks	59 (73.8%)	58 (82.9%)	64 (73.6%)	71 (87.7%)	252 (79.2%)
>24 weeks	3 (3.8%)	2 (2.9%)	7 (8.0%)	2 (2.5%)	14 (4.4%)
Number of doses					
n	80	70	87	81	318
Mean (SD)	5.1 (1.7)	5.5 (1.3)	5.4 (1.3)	5.6 (1.3)	5.4 (1.4)
Median	6.0	6.0	6.0	6.0	6.0
Range	1–6	1–6	1–6	1–6	1–6
Total cumulative dose (mg)					
n	0	70	87	81	238
Mean (SD)	NE (NE)	409.1 (98.6)	784.2 (204.4)	1666.7 (393.3)	974.2 (584.5)
Median	NE	450.0	900.0	1800.0	900.0
Range	NE–NE	75–450	150–913	300–1800	75–1800

Table 31 Extent of Exposure to Study Drug: Safety-Evaluable Population (cont.)

	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Missed doses					
n	80	70	87	81	318
0	60 (75.0%)	58 (82.9%)	69 (79.3%)	72 (88.9%)	259 (81.4%)
1	3 (3.8%)	1 (1.4%)	5 (5.7%)	1 (1.2%)	10 (3.1%)
2	2 (2.5%)	4 (5.7%)	3 (3.4%)	0	9 (2.8%)
3	2 (2.5%)	1 (1.4%)	3 (3.4%)	3 (3.7%)	9 (2.8%)
4	6 (7.5%)	4 (5.7%)	6 (6.9%)	0	16 (5.0%)
5	7 (8.8%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	15 (4.7%)

NE=not evaluable.

Note: Duration of study drug exposure was defined as the date of the last treatment visit minus the date of the first study drug administration +1 day +4 weeks (28 days).

Source: page 596.

7.3 COMMON ADVERSE EVENTS

A total of 237 patients (74.5%) experienced at least one treatment-emergent AE (see Table 32) while on study. The majority of treatment-emergent AEs in all treatment arms were mild or moderate (see page 598 and page 618).

Table 32 Adverse Events, Deaths, and Withdrawals by Study Treatment: Safety-Evaluable Population

Genentech, Inc. Study q4881g
Xolair (Omalizumab) Xolair in Refractory Chronic Idiopathic Urticaria (CIU)

Table 14.3/2
Overall AE Profile: Adverse Events, Deaths, and Withdrawals by Study Treatment
Safety-Evaluable Patients

	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Total number of patients with at least one AE	53 (66.3%)	55 (78.6%)	72 (82.8%)	57 (70.4%)	237 (74.5%)
Total number of AEs	180	164	241	168	753
Total number of deaths	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Total number of patients withdrawn from study due to an AE	2 (2.5%)	(0.0%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
Total number of patients with at least one					
Serious AE	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
Serious AE leading to withdrawal from treatment	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
Serious AE leading to dose held	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Serious AE suspected to be caused by study drug	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
AE leading to withdrawal from treatment	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)
AE leading to dose held	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
AE suspected to be caused by study drug	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
Severe AE	8 (10.0%)	7 (10.0%)	8 (9.2%)	13 (16.0%)	36 (11.3%)

Includes adverse events with onset dates on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_ovrl)
Database (OPEN) Datasets (dae pat)
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Treatment-emergent AEs have been summarized separately for the treatment and the follow-up periods (on the basis of the date of onset of the event) and over the whole study (Day 1 through Week 40).

7.3.1 Common Adverse Events During the Treatment Period

The proportions of patients who experienced at least one treatment-emergent AE during the treatment period (Day 1 to Week 24 or the date of treatment discontinuation) was higher in the omalizumab group than the placebo group: 58.6% (41 out of 70 patients) in the omalizumab 75-mg group, 69.0% (60 out of 87 patients) in the omalizumab 150-mg group, 56.8% (46 out of 81 patients) in the omalizumab 300-mg group, and 51.3% (41 out of 80 patients) in the placebo group (see page 552).

Table 33 presents the treatment-emergent AEs reported by ≥3% of patients in any treatment group during the treatment period. Of all patients, 59.1% experienced at least one treatment–emergent event. Overall, the most commonly affected SOC in patients during the treatment period was infections and infestations (28.3%), followed by skin and subcutaneous tissue disorders (14.2%), nervous system disorders (10.4%), musculoskeletal and connective tissue disorders (9.4%), and general disorders and administration site conditions (6.0%). The incidence of infections and infestations, and skin and subcutaneous tissue disorders was highly variable among the omalizumab groups but showed no trend to increased rates in the omalizumab groups. However, the incidence of nervous system disorders, musculoskeletal and connective tissue disorders, and general disorders and administration site conditions was consistently higher in all omalizumab groups than in the placebo group without a dose-response pattern.

Overall, the most common treatment-emergent AEs by preferred term, during the treatment period, was nasopharyngitis (10.4%) which was within the infections and infestations SOC. The incidence of nasopharyngitis was variable among the groups but not elevated above placebo rates in any omalizumab groups. The next most commonly reported event by preferred term was headache, with 6.0% of all patients reporting at least one event during the treatment period. As shown in Table 33, the incidence of headache was higher in the omalizumab groups with the highest incidence occurring in omalizumab 150-mg group (9.2%) compared to the incidence in the placebo group (2.5%). Other events with a higher incidence in the omalizumab groups were: arthralgia (by preferred term) in the musculoskeletal and connective tissue disorders, where the highest incidence was observed in the omalizumab 150-mg group (5.7%) compared to the incidence in the placebo group (0%) and injection-site reactions (by high-level term) in the general disorders and administration site conditions SOC, where the omalizumab 300-mg group was associated with the highest incidence (3.7%) compared to the incidence in placebo (1.3%) (see page 552).

The event types, during the treatment period, that account for the higher AE rate in the omalizumab groups were headaches (nervous system disorders SOC), arthralgia

(musculoskeletal and connective tissue disorders SOC), and injection-site reactions (general disorders and administration site conditions SOC).

Table 33 Treatment-Emergent Adverse Events during Treatment Period with Incidence ≥3% in Any Treatment Group: Safety-Evaluable Population

MedDRA System Organ Class Preferred Term	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any AEs	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
General disorders and administration site conditions					
Overall	2 (2.5%)	3 (4.3%)	7 (8.0%)	7 (8.6%)	19 (6.0%)
Pyrexia	1 (1.3%)	1 (1.4%)	3 (3.4%)	0	5 (1.6%)
Infections and infestations					
Overall	22 (27.5%)	20 (28.6%)	32 (36.8%)	16 (19.8%)	90 (28.3%)
Nasopharyngitis	10 (12.5%)	3 (4.3%)	11 (12.6%)	9 (11.1%)	33 (10.4%)
Sinusitis	4 (5.0%)	5 (7.1%)	4 (4.6%)	3 (3.7%)	16 (5.0%)
Bronchitis	5 (6.3%)	4 (5.7%)	2 (2.3%)	1 (1.2%)	12 (3.8%)
Upper respiratory tract infection	3 (3.8%)	3 (4.3%)	3 (3.4%)	1 (1.2%)	10 (3.1%)
Urinary tract infection	2 (2.5%)	1 (1.4%)	4 (4.6%)	1 (1.2%)	8 (2.5%)
Fungal infection	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
Musculoskeletal and connective tissue disorders					
Overall	2 (2.5%)	7 (10.0%)	12 (13.8%)	9 (11.1%)	30 (9.4%)
Arthralgia	(0.0%)	1 (1.4%)	5 (5.7%)	3 (3.7%)	9 (2.8%)
Pain in extremity	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
Nervous system disorders					
Overall	4 (5.0%)	7 (10.0%)	14 (16.1%)	8 (9.9%)	33 (10.4%)
Headache	2 (2.5%)	4 (5.7%)	8 (9.2%)	5 (6.2%)	19 (6.0%)
Migraine	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)

Table 33 Treatment-Emergent Adverse Events during Treatment Period with Incidence ≥ 3% in Any Treatment Group: Safety-Evaluable Population (cont.)

MedDRA System Organ Class Preferred Term	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Respiratory, thoracic and mediastinal disorders					
Overall	10 (12.5%)	5 (7.1%)	12 (13.8%)	4 (4.9%)	31 (9.7%)
Oropharyngeal pain	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
Cough	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
Skin and subcutaneous tissue disorders					
Overall	13 (16.3%)	13 (18.6%)	10 (11.5%)	9 (11.1%)	45 (14.2%)
Urticaria	6 (7.5%)	5 (7.1%)	4 (4.6%)	2 (2.5%)	17 (5.3%)
Idiopathic urticaria	2 (2.5%)	5 (7.1%)	1 (1.1%)	1 (1.2%)	9 (2.8%)
Angioedema	3 (3.8%)	(0.0%)	(0.0%)	3 (3.7%)	6 (1.9%)

AE=adverse event; MedDRA=Medical Dictionary for Regulatory Activities.

Note: Multiple occurrences of a specific AE for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class.

Includes treatment-emergent adverse events that started on or after the first treatment date.

A treatment-emergent AE was defined as any AE reported at the time of or after the first dose of study drug.

Source: page 643.

7.3.2 Common Adverse Events During the Follow-up Period

During the follow-up period (Week 24 to Week 40), 47.5% of the patients experienced at least one AE (see page 645). The incidence of treatment-emergent AEs was higher in the omalizumab group than the placebo group: 51.4% (36 out of 70 patients) in the omalizumab 75-mg, 51.7% (45 out of 87 patients) omalizumab 150-mg, and 46.9% (38 out of 81 patients) omalizumab 300-mg, and 40% (32 out of 80 patients) in the placebo group.

Overall, the most commonly affected SOC in patients during the follow-up period was infections and infestations (19.8%), followed by skin and subcutaneous tissue disorders (17.6%), musculoskeletal and connective tissue disorders (5.0%), and respiratory, thoracic and mediastinal disorders (5.0%). The incidence of infections and infestations, and respiratory, thoracic and mediastinal disorders were highly variable among the omalizumab groups but showed no trend to increased rates in the omalizumab groups. However, the incidence of skin and subcutaneous tissue disorders was higher in the omalizumab 75 mg (21.4%) and 300 mg (22.2%) than in the placebo group (15.0%). In addition, the incidence of musculoskeletal and connective tissue disorders was higher in the omalizumab 150 mg (5.7%) and 300 mg (6.2%) than in the placebo group (3.8%).

Overall, the most commonly reported event by preferred term, during the follow-up period, was idiopathic urticaria (8.2% of patients). The incidence of idiopathic urticaria was higher in the omalizumab groups (8.6% [6 out of 70 patients] in the omalizumab 75-mg group, 6.9% [6 out of 87 patients] in the omalizumab 150-mg group, 13.6% [11 out of 81 patients] in the omalizumab 300-mg group) than in the placebo group (3.8% ([3 out of 80 patients]). The next most commonly reported event by preferred term was nasopharyngitis (4.4% of patients; 2 patients [2.9%], 3 patients [3.4%], 2 patients [2.5%], and 7 patients [8.8%] in the omalizumab 75-mg, 150-mg, 300-mg, and placebo groups, respectively). Other events with a higher incidence in the omalizumab groups were: sinusitis in the infections and infestations SOC (1.4% [1 out of 70 patients] in the omalizumab 75-mg group, 4.6% [4 out of 87 patients] in the omalizumab 150-mg group, 2.5% [2 out of 81 patients] in the omalizumab 300-mg group, and 1.3% [1 out of 80 patients] in the placebo group); upper respiratory tract infection in the incidence of infections and infestations SOC (4.3% [3 out of 70 patients] in the omalizumab 75-mg group, 2.3% [2 out of 87 patients] in the omalizumab 150-mg group, 3.7% [3 out of 81 patients] in the omalizumab 300-mg group, and 0% in the placebo group); headaches in the nervous system disorders SOC (1.4% [1out of 70 patients] in the omalizumab 75-mg group, 4.6% [4 out of 87 patients] in the omalizumab 150-mg group, 2.5% [2 out of 81 patients] in the omalizumab 300-mg group, and 1.3% [1 out of 80 patients] in the placebo group); and arthralgia in the musculoskeletal and connective tissue disorders SOC (4.3% [3 out of 70 patients] in the omalizumab 75-mg group, 2.3% [2 out of 87 patients] in the omalizumab 150-mg group, 2.5% [2 out of 81 patients] in the omalizumab 300-mg group, and 0% in the placebo group).

The event types, during the follow-up period, that account for the higher AE rate in the omalizumab group were idiopathic urticaria (skin and subcutaneous tissue disorders SOC), sinusitis and upper respiratory tract infection (infections and infestations SOC), headaches (nervous system disorders SOC), and arthralgia (musculoskeletal and connective tissue disorders SOC).

A listing of the treatment-emergent AEs that occurred in the 4 patients who received open-label omalizumab during the follow-up period can be found on page 1009. There were 4 treatment-emergent AEs occurring in 4 of these patients: 3 events moderate in intensity (fatigue [placebo], pharyngitis streptococcal [placebo], insomnia [omalizumab 75 mg]) and 1 event mild in intensity (nasopharyngitis [placebo]).

7.3.3 Common Adverse Events While on Study

Treatment-emergent AEs occurring in ≥3% of patients in any treatment group while on study are summarized on page 657. The proportions of patients who experienced at least one treatment-emergent AE while on study was higher in the omalizumab group than the placebo group: 78.6% (55 out of 70 patients) in the omalizumab 75-mg group, 82.8% (72 out of 87 patients) in the omalizumab 150-mg group, 70.4% (57 out of 81

patients) in the omalizumab 300-mg group, and 66.3% (53 out of 80 patients) in the placebo group (see page 657).

Overall, the most commonly affected SOC while on study was infections and infestations (40.9%), followed by skin and subcutaneous tissue disorders (28.0%), nervous system disorders (14.5%), and musculoskeletal and connective tissue disorders (12.3%). The incidence of infections and infestations was higher in the omalizumab 150-mg group (49.4%) than the placebo group (40.0%). The incidence of the skin and subcutaneous tissue disorders was higher in the omalizumab 75-mg (35.7%) and 300-mg (30.9%) groups than the placebo group (25.0%). The incidence of nervous system disorders and musculoskeletal and connective tissue disorders was higher in all omalizumab groups than in the placebo group (see page 657).

Overall, the most common treatment-emergent AE by preferred term, while on study, was nasopharyngitis (14.2% of patients), followed by idiopathic urticaria (10.1% of patients), and headache (8.5% of patients). The incidence of nasopharyngitis was highest in the placebo group (20%). The incidence of idiopathic urticaria AE was higher in all omalizumab treatment groups than in the placebo group: omalizumab 75-mg group (14.3%); omalizumab 150-mg (6.9%), omalizumab 300-mg (13.6%), and placebo (6.3%). The incidence of headaches was higher in the omalizumab groups: omalizumab 150-mg group (13.8%), omalizumab 75-mg (7.1%), omalizumab 300-mg (8.6%), than in the placebo (3.8%) group. Another event with a higher incidence in the omalizumab groups was: arthralgia in the musculoskeletal and connective tissue disorders SOC (4.3% [3 out of 70 patients] in the omalizumab 75-mg group, 5.7% [5 out of 87 patients] in the omalizumab 150-mg group, 4.9% [4 out of 81 patients] in the omalizumab 300-mg group, and 0% in the placebo group).

The event types that account for the higher AE rate in the omalizumab group while on study were idiopathic urticaria (skin and subcutaneous tissue disorders SOC), headaches (nervous system disorders SOC), and arthralgia (musculoskeletal and connective tissue disorders SOC).

For details on all treatment-emergent AEs that occurred while on study, see page 598. A patient listing of all AEs is summarized on page 1058. For details on AESI see Section 7.9.

7.3.4 Adverse Events Suspected to be Caused by Study Drug

A total of 50 treatment-emergent AEs suspected to be caused by study drug, as assessed by the investigator, were reported in 33 patients (see Table 34). The proportions of patients experiencing at least one AE suspected to be caused by study drug increased with increasing omalizumab dose with the lowest proportion of patients in the placebo group and the highest in the omalizumab 300-mg group (see page 660). The number of events reported also increased over increasing doses of omalizumab.

The majority of the related AEs (34 of 50) were mild and of the 14 AEs with moderate intensity, 10 were in the omalizumab 300-mg group. Two severe AEs were reported, one each in the omalizumab 150-mg and 300-mg groups (see Table 34).

Table 34 Adverse Events Suspected to be Caused by Study Drug: Safety-Evaluable Population

	Severity	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Number of events	Any	5	10	13	22	50
	Mild	3	9	11	11	34
	Moderate	2	1	1	10	14
	Severe	0	0	1	1	2
Number (%) of patients	Any	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
	Mild	2 (2.5%)	5 (7.1%)	7 (8.0%)	8 (9.9%)	22 (6.9%)
	Moderate	2 (2.5%)	1 (1.4%)	1 (1.1%)	5 (6.2%)	9 (2.8%)
	Severe	0	0	1 (1.1%)	1 (1.2%)	2 (0.6%)

Note: Patients summarized by the maximum severity of an event occurrence.
Source: page 660 and page 1101.

Overall, the most commonly affected SOCs were general disorders and administration site conditions (11 events in 9 patients), nervous system disorders (11 events in 10 patients), skin and subcutaneous tissue disorders (10 events in 8 patients) and gastrointestinal disorders (7 events in 4 patients) (see Table 35).

In the general disorders and administration site conditions SOC, all 11 events were mild (7 events) or moderate (4 events) in intensity. The types of events were primarily injection-site reactions, oedema, and swelling. All of these events occurred within a week of a study drug injection (see page 1101).

In the nervous system disorders SOC, 10 of the 11 events were mild and consisted primarily of dizziness and headache. The majority of these events had an onset within 1 day of study drug administration (see page 1101). Patient [redacted] in the omalizumab 300-mg group, experienced a severe headache on Day 30, the same day the patient received the second dose of study drug. The patient received a third dose of study drug while severe headache event was still ongoing and received treatment (codeine, when necessary) for the severe headache. The study drug was subsequently permanently discontinued as a result of headache. The event resolved on Day 136. No events were reported in patients in the placebo group. For further details on Patient [redacted] see page 221.

In the skin and subcutaneous tissue disorders SOC, all 10 events were mild (3 events) or moderate (7 events) in intensity. The most commonly reported events were related to

hair loss: 1 mild event of alopecia in the omalizumab 150-mg group, 1 moderate event of alopecia in the 75-mg group, 2 moderate events of alopecia in the omalizumab 300-mg group with one of the patients in the 300-mg group also experiencing a moderate event of madarosis (see page 660 and page 1101). No alopecia events were reported in patients in the placebo group. The remaining events consisted of one event each of eczema, pain of skin, pruritus, urticaria and angioedema (see page 660). The event of angioedema was moderate in intensity and occurred in Patient [redacted] in the omalizumab 300-mg group on the day the patient received their third dose of study drug. This patient also experienced an injection-site reaction (suspected to be caused by study drug) on the same day. No-action was taken and the patient continued to receive study drug treatment (see page 1101).

In the gastrointestinal disorders SOC, 6 of 7 events reported were mild in intensity. The event types consisted of one each of GERD and lip swelling, two events each of diarrhea and abdominal pain upper, and one event of abdominal pain lower (see page 660). One patient (Patient [redacted]) in the omalizumab 150-mg group experienced a mild event of upper abdominal pain the day after receiving their second dose of study drug and a severe event of lower abdominal pain 4 days after that same study treatment. The investigator suspected the events were caused by study drug. The abdominal pain did not require treatment and was assessed by the investigator as resolved on the following day. The study drug was permanently discontinued due to other AEs experienced by this patient, but not as a result of these abdominal pain AEs. For further details on Patient [redacted] see page 216. No events were reported in patients in the placebo group.

The dose-dependent trend in AE rates suspected to be caused by study drug was not clustered by a specific AE type. The largest numerical differences occurred between the omalizumab 300-mg and placebo groups for the related AE headache (1 patient in the omalizumab 75-mg group, 2 patients in the omalizumab 150-mg group, 4 patients in the omalizumab 300 mg, and no patients in the placebo group) and injection-site reactions (1 patient in the omalizumab 150-mg group, 3 patients in the omalizumab 300-mg group and 1 patient in the placebo group) (see page 660).

The 33 patients who experienced the 50 treatment-emergent AEs suspected to be caused by study drug were distributed across 21 of the 53 sites which enrolled patients in the study. Nearly half (16 of 33) of the patients reporting AEs suspected to be caused by study drug were enrolled at non-US sites where less than a third (31%) of all patients in the study were enrolled.

Table 35 Number of Events suspected to be caused by study drug by System Organ Class and Severity: Safety-Evaluable Population

MedDRA System Organ Class	Severity	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	Total Events
Blood and lymphatic system disorders [a]	Mild	0	0	0	1	1
Ear and labyrinth disorders	Mild	1	0	0	0	1
Eye disorders	Moderate	0	0	0	2	2
Gastrointestinal disorders	Mild	0	3	2	1	7
	Severe	0	0	1	0	
General disorders and administration site conditions	Mild	1	1	2	3	11
	Moderate	1	0	0	3	
Infections and infestations	Mild	0	0	2	0	2
Investigations	Mild	0	0	1	1	2
Musculoskeletal and connective tissue disorders	Mild	0	1	1	0	3
	Moderate	0	0	0	1	
Nervous system disorders	Mild	0	4	2	4	11
	Severe	0	0	0	1	
Skin and subcutaneous tissue disorders	Mild	1	0	1	1	10
	Moderate	1	1	1	4	

LLN = lower limit of normal; MedDRA = Medical Dictionary for Regulatory Activities

[a] Patient [redacted] (omalizumab 300-mg group) had an AE reported for thrombocytopenia that was assessed by the investigator as study drug related. The basis for this AE was a single platelet count below the LLN (129×10^9/L at the Week 4 visit, with LLN = 140×10^9/L). The platelet counts at screening and Day 1 were 149×10^9/L and 196×10^9/L, respectively. The Week 8 to Week 40 range of platelet count values was 144×10^9/L to 175×10^9/L with no overall trend in the values observed during the entire study including screening (pre-randomization) values.

Source: page 660 and page 1101.

7.4 ADVERSE EVENTS BY INTENSITY

7.4.1 Adverse Events by Intensity During the Treatment Period

During the treatment period, 21 patients (6.6%) experienced a severe AE: 5 patients (7.1%) in the omalizumab 75-mg group, 5 patients (5.7%) in the omalizumab 150-mg group, 3 patients (3.7%) in the omalizumab 300-mg group, and 8 patients (10.0%) in the placebo group (see page 569). The most common severe treatment-emergent AE reported in patients during the treatment period by SOC was skin and subcutaneous tissue disorders, which occurred in 9 patients (2.8%) (high-level terms: urticarias, angioedemas, pruritus NEC): 4 patients (5.7%) in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group. The second most common severe treatment-emergent AE reported in patients during the treatment period by SOC was musculoskeletal and connective tissue disorders, which occurred in 4 patients (1.3%) (high-level terms: musculoskeletal and connective tissue pain and discomfort, joint related signs and symptoms, muscle weakness conditions): 1 patient (1.4%) in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and no patients in the placebo group. The third most common severe treatment-emergent AE reported in patients during the treatment period by SOC was nervous system disorders, which occurred in 2 patients (0.6%) (high-level terms: headaches NEC): 1 patient in the omalizumab 300-mg group and 1 patient in the placebo group.

7.4.2 Adverse Events by Intensity During the Follow-up Period

During the follow-up period, 18 patients (5.7%) experienced a severe AE. The incidence of severe treatment-emergent AEs was higher in the 300-mg group (10 patients; 12.3%) than in all other treatment groups: 3 patients (4.3%) in the omalizumab 75-mg; 4 patients (4.6%) in the omalizumab 150-mg and 1 patient (1.3%) in the placebo groups (see page 664). The most common severe treatment-emergent AE reported in patients during the follow-up period by SOC was skin and subcutaneous tissue disorders, which occurred in 12 patients (3.8%): 2 patients (2.9%) in the omalizumab 75-mg group, 3 patients (3.4%) in the omalizumab 150-mg group, 7 patients (8.6%) in the omalizumab 300-mg group, and no patients in the placebo group. The next most common severe AE by SOC was immune system disorders, which occurred in 2 patients (0.6%), both in the omalizumab 300-mg group (2.5%) and musculoskeletal and connective tissue disorders which occurred in 2 patients (0.6%): 1 patient (1.1%) in the omalizumab 150-mg group and 1 patient (1.3%) in the placebo group. The most common severe treatment-emergent AE reported in patients during the follow-up period by high-level term was urticarias, which occurred in 12 patients (3.8%): 2 patients (2.9%) in the omalizumab 75-mg group, 3 patients (3.4%) in the omalizumab 150-mg group, and 7 patients (8.6%) in the omalizumab 300-mg group.

7.4.3 Adverse Events by Intensity While on Study

Over the whole study (treatment period and follow-up period) a total of 36 patients (11.3%) experienced at least one severe AE: 7 patients (10.0%) in the omalizumab 75-mg group, 8 patients (9.2%) in the omalizumab 150-mg group, 13 patients (16.0%) in the omalizumab 300-mg group, and 8 patients (10.0%) in the placebo group (see page 618).

7.5 DEATHS

There were no deaths reported in this study (see page 1105).

7.6 SERIOUS ADVERSE EVENTS

7.6.1 Serious Adverse Events During the Treatment Period

During the treatment period, 9 patients (2.8%) experienced an SAE: 2 patients (2.9%) in the omalizumab 75-mg group, 3 patients (3.4%) in the omalizumab 150-mg group, no patients in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group (see Table 36). The reported events by preferred term were gastrooesophageal reflux disease and urticaria in the omalizumab 75-mg group; angina unstable, appendicitis, pain in extremity, and hypertension in the omalizumab 150-mg group; radius fracture, Type 2 diabetes mellitus, cervical dysplasia, and chronic obstructive pulmonary disease (COPD) in the placebo group. It was reported that Patient [redacted] (placebo group) experienced an event of cervical dysplasia; however, after receiving the pathology report for this patient post-database lock, it was determined that this patient experienced a cervical adenocarcinoma in situ. For further details on Patient [redacted] please see Section 7.9.5. None of the reported SAEs were assessed by the investigator as related to study drug (see page 1106).

Table 36 Patients with Treatment−Emergent Serious Adverse Events Occurring During the Treatment Period: Safety-Evaluable Population

Preferred Term	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any adverse events	4 (5.0%)	2 (2.9%)	3 (3.4%)	0	9 (2.8%)
Angina unstable	0	0	1 (1.1%)	0	1 (0.3%)
Gastrooesophageal reflux disease	0	1 (1.4%)	0	0	1 (0.3%)
Appendicitis	0	0	1 (1.1%)	0	1 (0.3%)
Radius fracture	1 (1.3%)	0	0	0	1 (0.3%)
Type 2 diabetes mellitus	1 (1.3%)	0	0	0	1 (0.3%)
Pain in extremity	0	0	1 (1.1%)	0	1 (0.3%)
Cervical dysplasia	1 (1.3%) [a]	0	0	0	1 (0.3%)
Chronic obstructive pulmonary disease	1 (1.3%)	0	0	0	1 (0.3%)
Urticaria	0	1 (1.4%)	0	0	1 (0.3%)
Hypertension	0	0	1 (1.1%)	0	1 (0.3%)

Notes: Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent serious adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

A treatment-emergent AE was defined as any AE reported at the time of or after the first dose of study drug.

[a] In the pathology report received post-database lock, the cervical dysplasia event experienced by Patient [redacted] (placebo group) was found to be a cervical adenocarcinoma in situ.

Source: page 592.

7.6.2 Serious Adverse Events During the Follow-up Period

During the follow-up period, 5 patients (1.6%) experienced at least one SAE (see Table 30): 2 patients (2.3%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 1 patient (1.3%) in the placebo group. The following treatment-emergent SAE reported by preferred term each occurred in 1 patient (0.3%): urticaria (omalizumab 150-mg group), angioedema (omalizumab 150-mg group), abortion induced (omalizumab 150-mg group), anaphylactic reaction (omalizumab 300-mg group), shock hypoglycaemic (omalizumab 300-mg group), and idiopathic urticaria (placebo group). Patient [redacted], in the omalizumab 300-mg group, experienced a serious anaphylactic reaction (see page 1106). The investigator confirmed this event as a reaction to dipyrone and assessed the event as not related to the study drug. For

more details on Patient [redacted] see Section 7.9.1. None of the reported SAEs were assessed by the investigator as related to study drug (see page 1106).

7.6.3 Serious Adverse Events While on Study

A total of 14 patients (4.4%) experienced an SAE while on study (treatment period and follow-up period) (see Table 37). The proportions of patients with reported treatment-emergent SAEs (up to Week 40) were: 2 patients (2.9%) in the omalizumab 75-mg group, 5 patients (5.7%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 5 patients (6.3%) in the placebo group. The treatment-emergent SAE reported by preferred term each occurred in 1 patient (0.3%) except for urticaria which occurred in 2 patients (0.6%) (see Table 37). The majority of the SAEs were severe in intensity (see page 1106). None of the reported SAEs were assessed by the investigator as related to study drug (see page 1106).

Table 37 Patients with Treatment-Emergent Serious Adverse Events Occurring While on Study: Safety-Evaluable Population

Preferred Term	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any adverse events	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
Angina unstable	0	0	1 (1.1%)	0	1 (0.3%)
Gastrooesophageal reflux disease	0	1 (1.4%)	0	0	1 (0.3%)
Anaphylactic reaction	0	0	0	1 (1.2%)	1 (0.3%)
Appendicitis	0	0	1 (1.1%)	0	1 (0.3%)
Radius fracture	1 (1.3%)	0	0	0	1 (0.3%)
Type 2 diabetes mellitus	1 (1.3%)	0	0	0	1 (0.3%)
Shock hypoglycaemic	0	0	0	1 (1.2%)	1 (0.3%)
Pain in extremity	0	0	1 (1.1%)	0	1 (0.3%)
Cervical dysplasia	1 (1.3%) [a]	0	0	0	1 (0.3%)
Chronic obstructive pulmonary disease	1 (1.3%)	0	0	0	1 (0.3%)
Urticaria	0	1 (1.4%)	1 (1.1%)	0	2 (0.6%)
Idiopathic urticaria	1 (1.3%)	0	0	0	1 (0.3%)
Angioedema	0	0	1 (1.1%)	0	1 (0.3%)
Abortion induced	0	0	1 (1.1%)	0	1 (0.3%)
Hypertension	0	0	1 (1.1%)	0	1 (0.3%)

Notes: Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

A treatment-emergent AE was defined as any AE reported at the time of or after the first dose of study drug.

[a] In the pathology report received post-database lock, the cervical dysplasia event experienced by Patient [redacted] (placebo group) was found to be a cervical adenocarcinoma in situ.

Source: page 679.

7.6.4 Brief Summary of Each Patient with a Serious Adverse Event

Omalizumab 75-mg group:

Patient [redacted] a [redacted] year-old female randomized to omalizumab 75 mg, experienced chest pain and was hospitalized on Day 145 and on the same day was diagnosed with GERD (last dose of study drug prior to this event was on Day 142). She had negative

cardiac enzymes and had no specific changes on the electrocardiogram. It was reported that the chest pain was due to worsening of GERD. The chest pain and worsening of gastroesophageal reflux resolved on Days 145 and 146, respectively. The investigator assessed the event of worsening of GERD as serious and not related to the study drug. On Day 402, the patient discontinued from the study and did not complete the follow-up period as a result of patient/legal guardian decision to withdraw.

Patient [redacted] a [redacted] year-old female randomized to omalizumab 75 mg, was diagnosed with severe acute exacerbation of urticaria on Day 142 (last dose of study drug prior to this event was on Day 141). The investigator assessed the event of urticaria as serious and not related to the study drug but related to disease under study. This event was subsequently submitted for blinded, external review by the Anaphylaxis Review Committee and was adjudicated as a case of anaphylaxis related to study drug. After receipt of additional information regarding the timing of study drug administration, the Anaphylaxis Review Committee re-assessed Patient [redacted] as a case of anaphylaxis not related to study drug. For details, see Section 7.9.1.

Omalizumab 150-mg group:

Patient [redacted] a [redacted] year-old female randomized to omalizumab 150 mg, received 6 doses of the study drug with the last dose administered on Day 138. On an unspecified date in [redacted], the urine-human chorionic gonadotropin (HCG) and an ultrasound scan was done and the patient was found to be pregnant. This was reported as drug exposure during pregnancy. On Day 257, the patient underwent therapeutic medical abortion and the pregnancy was terminated. The investigator considered the event of “therapeutic medical abortion” to be not related to the study drug.

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, developed severe unstable angina (angina unstable) and was admitted to the cardiological ward on Day 148 (last dose of study drug prior to this event was on Day 141). On Day 152, the event of unstable angina was considered resolved and the patient was discharged on that day. This patient had medical and surgical history which included inferior wall myocardial infarction, circumflex coronary artery angioplasty, right coronary and left anterior descending coronary artery bypass grafts, coronary angioplasty. Her concurrent conditions at enrollment included hypothyroidism post-thyroidectomy, hyperlipidemia, coronary artery disease, hypertension and status post myocardial infarction.
The investigator assessed the event of unstable angina as serious and not related to the study drug and related to concurrent illness. The patient discontinued from the study as a result of unstable angina on Day 169.

Patient [redacted] a [redacted] year-old male randomized to omalizumab 150 mg, developed sudden uvula angioedema (Quincke’s) with exacerbation of chronic idiopathic urticaria on Day 30 (last dose of study drug prior to these events was on Day 29). On the same day (Day 30), the patient was hospitalized and diagnosed with severe angioedema and

urticaria. No respiratory compromise was noted. He was treated with ciclosporin, clemastine and desloratadine, and on Day 36, the events of angioedema and urticaria were considered to be resolved. This patient had a history of angioedema as of [redacted]. The investigator assessed the events of urticaria and angioedema as serious and not related to the study drug. The study drug was permanently discontinued as a result of urticaria and angioedema.

Patient [redacted] a [redacted]-year-old male randomized to omalizumab 150 mg, experienced abdominal pain, nausea, constipation, right quadrant pain, vomiting and was hospitalized on Day 98 and was diagnosed with moderate acute appendicitis (appendicitis) (last dose of study drug prior to this event was on Day 85). The patient underwent a laparoscopic appendectomy and recovered on Day 98. The investigator assessed the event of appendicitis as serious and not related to the study drug.

Patient [redacted] was a [redacted] year-old male randomized to omalizumab 150 mg. After database lock it was determined from the discharge summary and extended summary of safety that this patient was hospitalized due to severe idiopathic hypertension (hypertension) on Day 113 (dose of study drug prior to this event was administered on Day 87). He received treatment with lacidipine valsartan, torasemide, bisoprolol, doxazosin, amlodipine, allopurinol and tramadol and his blood pressure was controlled to values ranging from 120–130/80–90 mmHg and was considered resolved on Day 117. On Day 114, this patient experienced severe pain and dysfunction in right leg (pain in extremity) (last dose of study drug prior to this event was on Day 87). The hospital discharge diagnosis on Day 123 was embolism/thrombosis of unspecified vein, despite the essentially normal findings in the Doppler ultrasound exam. At enrollment, this patient's concurrent conditions included arthrosis, angioedema and hypertension for many years and was classified as having unstable hypertension. The investigator assessed the events of hypertension and pain in extremity as serious and not related to the study drug. In the investigator's opinion, concurrent illness was the suspected possible cause for these events.

Omalizumab 300-mg group:

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 300 mg, experienced severe anaphylactic reaction (dipyrone induced) on Day 283 (142 days after the receipt of the final dose of study drug). For details, see Section 7.9.1.

Patient [redacted] a [redacted]-year-old male randomized to omalizumab 300 mg, experienced severe hypoglycemic shock (shock hypoglycaemic) on Day 201 (last dose of study drug prior to this event was on Day 141) resulting in hospitalization. On Day 204, the event of shock hypoglycaemic was considered resolved and the patient was discharged on enalapril, metformin, isophane insulin and insulin aspart. This patient's concurrent condition at enrollment included hypertension and Type 2 diabetes mellitus since [redacted]

The investigator assessed the event of shock hypoglycaemic as serious and not related to the study drug but related to concurrent illness.

Placebo group:

Patient [redacted] a [redacted]-year-old female randomized to placebo, was diagnosed with severe cervical dysplasia on Day 10 (last dose of study drug prior to this event was on Day 1). However, after receiving the pathology report for this patient post-database lock, it was determined that this patient experienced cervical adenocarcinoma in situ. For details, see Section 7.9.5.

Patient [redacted] a [redacted]-year-old female randomized to placebo, was hospitalized as a result of severe flu-like infection with fever, dyspnea and developed bronchitis on Day 55 and was diagnosed with severe exacerbation of COPD by infection (last dose of study drug prior to this event was on Day 30). The patient was treated with amoxicillin/clavulanate potassium, clarithromycin, and oral prednisone. On Day 64, the event of exacerbated COPD was considered resolved and the patient was discharged in an improved general condition. This patient had a history of and her concurrent condition at enrollment included COPD. The investigator assessed the event of exacerbated COPD as serious and not related to the study drug but related to the concurrent illness, infection, and smoking. The study drug was permanently discontinued as a result of COPD.

Patient [redacted] a [redacted]-year-old female randomized to placebo, was diagnosed with mild worsening of chronic idiopathic urticaria (idiopathic urticaria) on Day 274 (last dose of study drug prior to this event was on Day 141), resulting in hospitalization. She was treated with intramuscular clemastine, levothyroxine sodium, topical hydrocortisone, and clobederm. On Day 281, the event of idiopathic urticaria was considered resolved and the patient was discharged from hospital in good general condition. The investigator assessed the event of idiopathic urticaria as serious and not related to the study drug but related to the disease under study.

Patient [redacted] a [redacted]-year-old male randomized to placebo, slipped and fell while taking a shower and was diagnosed with severe distal radius extension fracture-left (radius fracture) on Day 41 (last dose of study drug prior to this event was on Day 29) resulting in hospitalization for internal fixation of the fracture. On Day 135, the fracture was completely healed and the patient was in good condition. The same day (Day 135), the event of radius fracture was considered resolved. The Investigator assessed the event of radius fracture as serious and not related to the study drug but related to other concomitant medication. The patient discontinued from the study and did not complete the follow-up period as a result of disease progression on Day 177.

Patient [redacted] a [redacted]-year-old male randomized to placebo, was hospitalized as a result of severe Type 2 diabetes mellitus induced by corticosteroid therapy on Day 31 (last dose of study drug prior to this event was on Day 29). He was treated with insulin,

metformin, gliclazide, liraglutide and received dietary advice. On Day 36, the event of Type 2 diabetes mellitus was considered resolved and the patient was discharged. This patient's concurrent conditions included pytiriasis versicolor, iodine allergy, chlorine allergy, obesity, hypercholesterolemia and hypertension, and his grandmother had Type 2 diabetes. In addition, at screening this patient had high blood glucose, and at baseline this patient had polydipsia and polyuria associated with a 4 kg weight loss through Day 31. The investigator assessed the event of Type 2 diabetes mellitus as serious and not related to the study drug but related to concurrent condition.

A patient listing of all SAEs is summarized on page 1106. Narratives for patients who experienced an SAE are provided on (see page 187).

7.7 ADVERSE EVENTS THAT LED TO WITHDRAWAL OF STUDY TREATMENT

A total of 15 patients (4.7%) experienced a treatment-emergent AE that led to withdrawal of study drug: 2 patients (2.9%) in the omalizumab 75-mg group (Patients [redacted] and [redacted] , 4 patients (4.6%) in the omalizumab 150-mg group (Patients [redacted], [redacted] and [redacted]), 2 patients (2.5%) in the omalizumab 300-mg group (Patients [redacted] and [redacted]), and 7 patients (8.8%) in the placebo group (Patients [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted]) (see Table 38). The most commonly affected SOC was skin and subcutaneous tissue disorders, which occurred in 8 patients (2.5%): 2 patients (2.9%) in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and 3 patients (3.8%) in the placebo group. Within this SOC, the largest proportion of patients (5 patients, 1.6%) experienced events with the preferred term of urticaria, which occurred in 1 patient (1.4%) in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and 1 patient (1.3%) in the placebo group. The next most common preferred term was idiopathic urticaria (3 patients; 0.9%), followed by arthralgia (2 patients; 0.6%) and headache (2 patients; 0.6%). All other events that led to withdrawal of study treatment were each reported in 1 patient and included oedema peripheral, drug hypersensitivity, joint effusion, joint swelling, pain in extremity, asthma, COPD, and angioedema. Efforts were made to keep patients in the study for safety follow up when they were discontinued from study drug.

Table 38 Patients with Treatment-Emergent Adverse Events That Led to Discontinuation of Study Drug: Safety-Evaluable Population

Preferred Term	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)
Any adverse events	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)
Oedema peripheral	1 (1.3%)	0	0	0	1 (0.3%)
Drug hypersensitivity	1 (1.3%)	0	0	0	1 (0.3%)
Arthralgia	0	0	2 (2.3%)	0	2 (0.6%)
Joint effusion	0	0	1 (1.1%)	0	1 (0.3%)
Joint swelling	0	0	1 (1.1%)	0	1 (0.3%)
Pain in extremity	0	0	1 (1.1%)	0	1 (0.3%)
Headache	0	0	1 (1.1%)	1 (1.2%)	2 (0.6%)
Asthma	1 (1.3%)	0	0	0	1 (0.3%)
Chronic obstructive pulmonary disease	1 (1.3%)	0	0	0	1 (0.3%)
Urticaria	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
Idiopathic urticaria	2 (2.5%)	1 (1.4%)	0	0	3 (0.9%)
Angioedema	0	0	1 (1.1%)	0	1 (0.3%)

Notes: Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

A treatment-emergent AE was defined as any AE reported at the time of or after the first dose of study drug.

Source: page 589.

7.7.1 Adverse Events that Led to the Withdrawal from Study

There were 5 patients (1.6%) who withdrew from the study due to a treatment-emergent AE: 2 patient (2.3%) in the omalizumab 150-mg group, 1 patient (1.2%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group (see page 568 and page 1108):

- Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, withdrew from the study on Day 169 as a result of unstable angina. For more details see Section 7.6.4.
- Patient [redacted] a [redacted] year-old female randomized to omalizumab 150 mg, developed moderate joint pain (arthralgia) and headache on Day 26 (last dose of study drug prior to this event was on Day 1). She did not receive any treatment for both the events. On Day 42, the event of headache resolved and the outcome of arthralgia was not provided. The investigator assessed the events of arthralgia and headache as non-serious and not related to the study drug. The study drug was permanently

discontinued (last dose on Day 28) as a result of arthralgia and headache. The patient discontinued from the study and did not complete the follow-up period as a result of arthralgia and headache on Day 83.

- Patient [redacted] a [redacted]-year-old male randomized to omalizumab 300 mg, experienced severe pruriginous erythematous hives (urticaria) on Day 11 (last dose of study drug prior to this event was on Day 1). On the same day treatment with desloratadine was switched to ciclosporin, and on Day 12, the event of urticaria was considered resolved. The investigator assessed the event of urticaria as non-serious and not related to the study drug. Study drug was permanently discontinued due to urticaria. He received a single dose of the study drug administered on Day 1. The patient discontinued from the study and did not complete the follow-up period as a result of urticaria on Day 27.
- Patient [redacted] a [redacted] year-old female randomized to placebo, experienced severe worsening of chronic idiopathic urticaria (idiopathic urticaria) on Day 6 (last dose of study drug prior to this event was on Day 1). No treatment was reported for this event, and the outcome of the event of idiopathic urticaria was not provided. The investigator assessed the event of idiopathic urticaria as non-serious and not related to the study drug. The study drug was permanently discontinued as a result of idiopathic urticaria (last dose on Day 1). The patient discontinued from the study and did not complete the follow-up period as a result of idiopathic urticaria on Day 20.
- Patient [redacted] a [redacted]-year-old female randomized to placebo, developed moderate bilateral lower extremity edema (peripheral oedema) on Day 121 (last dose of study drug prior to this event was on Day 114). No treatment was provided for this event; however, the patient received treatment with prednisone for CIU. The outcome of the event was not provided. On Day 129, the patient experienced moderate idiopathic urticaria (chronic idiopathic urticaria exacerbation) which resolved the same day. The investigator assessed the event of peripheral oedema as non-serious and related to the study drug. The study drug was permanently discontinued as a result of peripheral oedema (last dose on Day 114). The patient discontinued from the study and did not complete the follow-up period as a result of peripheral oedema on Day 170.

The narratives for these treatment and study withdrawals are provided (see page 205).

7.8 ADVERSE EVENTS THAT LED TO DOSE MODIFICATION OR DOSE HELD

No study drug dose modifications were allowed during the study.

Study drug treatment was withheld for patient ([redacted] due to an AE (see page 568 and see page 1058).

Patient [redacted] (omalizumab 150 mg) experienced moderate skin exfoliation 1 day after the receipt of the last dose of study drug prior to this event. The patient's study drug treatment was withheld temporarily and a surgical procedure was performed to treat the

event. The event resolved 16 weeks later and the investigator considered the event to be not related to the study drug.

7.9 ADVERSE EVENTS OF SPECIAL INTEREST

AESI were identified using the search criteria outlined in Section 3.8.5.2. Among the AESI, anaphylaxis and serum sickness syndrome cases identified by the search criteria were further evaluated by a Sponsor clinical and safety scientist in an unblinded fashion. Flowcharts illustrating all cases excluded as a result of Sponsor clinical and safety review are included in Sections 7.9.1 and 7.9.6. Suspected cases of anaphylaxis identified by the Sponsor were submitted for blinded, external adjudication. Table 39 summarizes the incidence of AESI. Additional details are provided below.

Additional patient information presented in this section which is not found in the source listings is taken from the Sponsor's Clinical Database.

Table 39 Patients with Adverse Events of Special Interest Reported: Safety-Evaluable Population

Adverse Events of Special Interest	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)	Section
Anaphylaxis	0	1 (1.4%) [a]	0	1 (1.2%) [b]	2 (0.6%)	7.9.1
Churg-Strauss syndrome	0	0	0	0	0	7.9.2
Hypersensitivity	10 (12.5%)	3 (4.3%)	9 (10.3%)	9 (11.1%)	31 (9.7%)	7.9.3
Injection-site reactions	1 (1.3%)	1 (1.4%)	0	0	2 (0.6%)	7.9.4
Malignancies	0 [c]	0	0	0	0	7.9.5
Serum sickness syndrome [d]	0	0	0	0	0	7.9.6
Skin rash events	4 (5.0%)	5 (7.1%)	2 (2.3%)	3 (3.7%)	14 (4.4%)	7.9.7
Thrombocytopenia	0	0	0	1 (1.2%)	1 (0.3%)	7.9.8
Haemorrhages/bleeding	2 (2.5%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	10 (3.1%)	7.9.8
Haematopoietic cytopenias	0	0	2 (2.3%)	3 (3.7%)	5 (1.6%)	7.9.9
Arterial thrombotic events	0	0	1 (1.1%)	0	1 (0.3%)	7.9.10
Asthma/bronchospasm events	4 (5.0%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	13 (4.1%)	7.9.11
Liver related investigations, signs and symptoms	0	0	0	0	0	7.9.12

Adverse Events of Special Interest	Placebo (n=80)	Omalizumab 75 mg (n=70)	Omalizumab 150 mg (n=87)	Omalizumab 300 mg (n=81)	All Patients (n=318)	Section

[a] Patient [redacted] was reported as an exacerbation of urticaria, which was initially adjudicated by the Anaphylaxis Review Committee (ARC) as an event of anaphylaxis related to study drug but was subsequently re-assessed by the ARC as not related to study drug after receiving additional information where the criteria for temporal association was not fulfilled.

[b] Patient [redacted] experienced an anaphylaxis event after re-exposure to dipyrone 142 days after last dose of omalizumab 300 mg and was assessed as not related to study drug by the investigator and the ARC.

[c] One event of cervical adenoma in situ occurred in Patient [redacted] (placebo group). This event was originally reported as cervical dysplasia, but was later confirmed to be cervical adenocarcinoma in situ after the database lock, and therefore is not included in the table as a malignancy event.

[d] Serum sickness syndrome cases identified with the search criteria were evaluated by a Sponsor clinical and safety scientist (unblinded).

Source: Clinical review and page 682, page 683, page 684, page 685, page 686, page 687, page 688, page 689, page 690, page 691, page 692, page 693.

7.9.1 Anaphylaxis

The narrow search which contained preferred terms that represented core anaphylactic reaction terms (Category A) identified 1 patient (0.3%) (Patient [redacted] (see page 682). This core anaphylactic reaction (dipyrone induced) in Patient [redacted] occurred during the follow-up period (see page 1109).

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 300 mg, experienced severe anaphylactic reaction (dipyrone induced) on Day 283 (142 days after the receipt of the final dose of study drug). From Day 240 through Day 247, the patient was administered dipyrone 500 mg tablets for analgesia, without incident; subsequently, dipyrone was restarted on Day 283. Thirty minutes following the re-initiated dipyrone 500-mg dose on Day 283, the patient developed a severe anaphylactic reaction. The patient was treated with IV saline, clemastine fumarate, ranitidine, and prednisolone. On the same day, the event of anaphylactic reaction was considered resolved. The investigator considered the event to be serious and not related to the study drug and related to dipyrone, an agent known to cause anaphylaxis (Leone et al. 2005) (see Section 8 for more details). After a clinical review of the event by clinical science, it was determined that this event was an event of anaphylactic reaction not related to study drug but related to dipyrone.

Aside from the dipyrone case (narrow search result), the broad preferred term SMQ searches identified 70 patients (22.0%) who experienced signs and symptoms possibly indicative of anaphylactic reaction (Category B, C, D, or E): 52 patients in the omalizumab groups (17 patients [75-mg group], 22 patients [150-mg group], and 13 patients [300-mg group]) and 18 patients in the placebo group (see page 682). When the algorithmic search was applied, 13 patients (4.1%) were identified with possible components of anaphylaxis: 10 patients in the omalizumab groups (5 patients [75-mg group], 2 patients [150-mg group], and 3 patients [300-mg group]) and 3 patients in the placebo group (see page 682 and page 1109). The group of 13 patients identified by the algorithmic search is a subset of the 70 patients identified by the broad preferred term SMQ search. A by-patient listing of these events is provided (see page 1109).

After unblinded Sponsor clinical and safety review of the events identified from the broad and algorithmic searches, there was one case (Patient [redacted] [150-mg group]) of possible anaphylaxis from the algorithmic search that met the Sampson criteria (Sampson et al. 2006), as well as meeting the timing criteria (i.e., both events have occurred within 24 hours of each other and have occurred $\leq$72 hours of study drug administration). The cases excluded by timing criteria and based on unblinded Sponsor clinical and safety review are summarized in Figure 10.

Figure 10 Flow Diagram for Anaphylaxis Ascertainment Process

Category A = Core anaphylactic reaction terms; Category B = Upper airway/respiratory terms; Category C = Angioedema/urticaria/pruritus/flush terms; Category D = Cardiovascular/hypotension terms; Category E = Gastrointestinal terms.

[a] Both events have occurred within 24 hours of each other and have occurred ≤ 72 hours of study drug administration

[b] Sampson et al. 2006.

[c] All events were > 72 hours post study drug.

Source: page 1109.

The single case shown in Figure 10 (Patient [redacted]) that met the algorithmic search, as well as timing criteria applied by Sponsor clinical and safety scientists, is described briefly below.

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, experienced mild right upper abdominal pain (abdominal pain upper) on Day 31 (1 day after the last dose of study drug prior to this event), and a second episode of mild swelling upper lip (lip swelling) and severe hives exacerbation (urticaria) on Day 32 (2 days after the last dose of study drug prior to this event). On Days 33, 35, and 37 the lip swelling, abdominal pain upper and urticaria events were considered resolved, respectively.
The patient received no treatment for the abdominal pain upper and lip swelling events and there was no change in study drug as a result of these events. On Day 36, the patient received treatment with prednisone for CIU and developed mild joint swelling, pain in extremity and arthralgia. The patient permanently discontinued study treatment due to the events of urticaria, joint swelling, pain in extremity, and arthralgia.
The investigator assessed the event of abdominal pain upper as non-serious and related to study drug and the lip swelling event and urticaria as non-serious and not related to study drug. After a clinical review by clinical science, it was determined that this event was not anaphylaxis. The lip swelling was part of the patient's underlying disease and the patient had a medical history of similar events prior to enrolling in the study.

Aside from the cases identified using the narrow search (Patient [redacted] and the algorithmic search (Patient [redacted] , Patient [redacted] ([redacted] year old female randomized to omalizumab 75 mg) was also identified as a case of interest based on specific symptoms reported in the narrative. This patient was identified by the broad search (Category C; urticaria). Although the patient did not meet any other search term criteria for possible anaphylaxis (i.e., did not fulfill algorithmic search criteria), this patient was deemed to be a case of interest by the Sponsor's clinical and safety scientists since her detailed clinical records obtained from the investigator revealed additional symptoms of possible anaphylaxis that had not been reported by the site and thus was not captured by search terms. Specifically, on Day 142 which was 1 day after the last dose of study drug (study drug was administered at 9:50 am on Day 141) this patient reported abdominal cramps, sweating, diarrhea, acute hives on face and arms, itching, swollen face, and difficulty swallowing at 1:00 am leading to an emergency room visit. Her respiratory exam in the emergency room at 2:29 am was normal for auscultation with no wheezes noted and oxygen saturation was 100% on room air. Her exam was notable only for hives. No throat swelling was noted and her blood pressure was normal (110/70 mmHg), and she had no abdominal pain. She was diagnosed with severe acute exacerbation of urticaria. At 3.30 am the patient received treatment with methylprednisolone sodium succinate and epinephrine. The same day, after less than 2 hours of observation (at 4:07 am), the patient was discharged with no pain.
On Day 143, the day following event onset, the event of urticaria was considered resolved. Prior to enrollment, the patient had a history of allergic rhinitis, angioedema of

the lips and eyes, and multiple food allergies including fresh vegetables, pineapple, apples, peaches, and oranges, which result in lip swelling. She also had a long-standing epinephrine auto-injector prescription. The investigator assessed the event of urticaria as serious and not related to the study drug but related to disease under study. Based on unblinded review conducted by the Sponsor, this event was not considered to be a case of anaphylaxis; however, it was submitted for blinded, external adjudication as a suspected case.

The full narrative description for Patients [redacted] (dipyrone induced anaphylaxis), [redacted] and [redacted] can be found on page 187. All 3 cases of suspected anaphylaxis were submitted to an independent panel of experts (Anaphylaxis Review Committee) for review in a blinded fashion as described in the Charter for the Anaphylaxis Review Committee (reported separately). The adjudication results from the Anaphylaxis Review Committee are as follows: Patients [redacted] was a case of anaphylaxis not related to study drug, Patient [redacted] was not a case of anaphylaxis, and Patient [redacted] was a case of anaphylaxis related to study drug. For Patient [redacted] additional information regarding the timing of study drug administration was requested by the Anaphylaxis Review Committee post-adjudication. Upon receiving this information from the Sponsor, Patient [redacted] was re-assessed by the Anaphylaxis Review Committee as a case of anaphylaxis not related to study drug.

A full report of the clinical review conducted by the Anaphylaxis Review Committee is provided in a separate document.

7.9.2 Churg-Strauss Syndrome

There were no cases identified using the preferred term (allergic granulomatous angiitis) or broad search (high level group term vascular inflammations and the high level terms eosinophilic disorders and vasculitides NEC) for Churg-Strauss Syndrome (see page 683, page 1123).

7.9.3 Hypersensitivity

A search using the high-level term angioedemas and broad preferred terms identified 31 patients (9.7%) with a possible hypersensitivity reaction: 3 patients (4.3%) in the omalizumab 75-mg group, 9 patients (10.3%) in the omalizumab 150-mg group, 9 patients (11.1%) in the omalizumab 300-mg group, and 10 patients (12.5%) in the placebo group (see page 684). Of these 31 patients, 11 patients experienced asthma events (see page 684 and page 1124). The 11 patients who experienced an asthma AE had a prior history of asthma. The majority of events were reported to be mild or moderate.

Five events outlined below were reported as severe:

- Patient [redacted] a [redacted]year-old female randomized to omalizumab 150-mg, experienced severe asthma on Day 173. This patient had a history of asthma and prior to the asthma event, the patient had an upper respiratory infection starting on Day 88 which progressed to bacterial pneumonia on Day 146 (see page 1124 and page 1058).
- Patient [redacted] a [redacted]year-old male randomized to omalizumab 150 mg, developed sudden uvula angioedema (Quincke's) with exacerbation of chronic idiopathic urticaria on Day 30. This patient had a history of angioedema. No respiratory compromise was noted. The investigator assessed the events of urticaria and angioedema as serious and not related to the study drug. The study drug was permanently discontinued as a result of urticaria and angioedema. For more detail on this patient see Section 7.6.4 and patient narrative on page 201.
- For Patient [redacted], a [redacted]-year-old female randomized to omalizumab 300-mg, experienced severe drug hypersensitivity on Day 210 (see page 1124). The investigator considered the hypersensitivity reaction to be related to sulfamethoxazole and trimethoprim.
- Patient [redacted] a [redacted]-year-old female randomized to omalizumab 300-mg, developed severe angioedema on Day 74, 18 days after the most recent study drug administration (see page 1124). There was no history of angioedema reported. No treatment of the angioedema was required.
- Patient [redacted] a [redacted]year-old female randomized to placebo, experienced severe drug hypersensitivity on Day 82 (see page 1124). This patient was discontinued from study drug due to the drug hypersensitivity event. However, the investigator attributed the hypersensitivity experienced by Patient [redacted] to the patient's ibuprofen allergy. For more details see patient narrative on page 207.

Among the 20 patients with non-asthma hypersensitivity events, 2 patients (Patients [redacted] and [redacted] experienced an allergic reaction to non-omalizumab drugs, 8 patients (Patients [redacted] 1[redacted], [redacted] and [redacted]) experienced angioedema, 4 patients (Patients [redacted], [redacted] and [redacted] experienced face swelling, 2 patients (Patients [redacted] and [redacted] experienced chest discomfort, 2 patients (Patients [redacted] and [redacted] experienced drug hypersensitivity, 2 patients (Patients [redacted] and [redacted]) experienced hypersensitivity, and 2 patients (Patients [redacted] and [redacted]) experienced lip swelling. Among patients that reported drug hypersensitivity or hypersensitivity, two patients required treatment with epinephrine:.

- Patient [redacted] (omalizumab 300 mg): The event of drug hypersensitivity (Day 210, 69 days after last dose of study drug) was attributed by the investigator to trimethoprim/sulfamethoxazole administration (see page 1124). The event required an epinephrine injection as treatment.
- Patient [redacted] (omalizumab 300 mg): The acute hypersensitivity event on Day 186 (treated with epinephrine and dexamethasone) occurred 47 days after last dose of study drug.

All events were assessed by the investigator as not serious (except for Patient [redacted] described above) and not study drug related (except for Patients [redacted] and [redacted] (see page 1124).

Patient [redacted] (omalizumab150 mg) had a history of dust mite allergies and allergic rhinitis. On Day 4 the patient developed mild sore throat, worsened lip swelling, and worsened cheek swelling (assessed as related) (see page 1124). All three events resolved on the same day with no treatment.

Patient [redacted] (omalizumab 300 mg) had a medical history of allergic rhinitis. On Day 57, following the third study drug dosing which occurred on the same day, the patient exhibited an upper lip angioedema and urticaria around the injection site (assessed as related) (see page 1124). Treatment for the event was given but the type of treatment was not reported. The events resolved on the same day.

The narrative description for Patients [redacted] [redacted] and [redacted] mentioned above can be found on page 187.

7.9.4 Injection-Site Reactions

A search for injection site reactions (SMQ extravasation events [injection, infusion, and implants] search) identified 2 patients (0.6%) considered to have possible injection-site reactions: 1 patient (1.4%) in the omalizumab 75-mg group and 1 patient (1.3%) in the placebo group (see page 685).

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 75 mg, experienced a mild injection-site reaction (verbatim term: symmetric axillary swelling, bilateral) on Day 204, during the follow-up period when no study drug was given. The patient received no treatment for this injection-site reaction. The investigators assessed the event as not serious and not related to the study drug (see page 1129).

Patient [redacted] a [redacted]-year-old female randomized to placebo, experienced mild injection site pain (verbatim term: burning sensation at injection site while study drug administered) on Day 89, during the treatment period. The patient received no treatment for this event and was considered resolved on the same day (Day 89). The investigators assessed the event as not serious and related to the study drug (see page 1129).

7.9.5 Malignancies

A search for malignancies (SMQ malignancies search, including all four sub-SMQs malignancy related conditions, malignancy related therapeutic and diagnostic procedures, malignant or unspecified tumours, and tumour markers) identified no cases of malignancy (see page 688 and page 1130). At database lock, it was reported that Patient [redacted] experienced an event of cervical dysplasia; however, after receiving the pathology report for this patient post-database lock, it was determined that this patient experienced cervical adenocarcinoma in situ (see page 187).

Patient [redacted] a [redacted]-year-old female randomized to placebo, was diagnosed with severe cervical dysplasia on Day 10 (nine days after the receipt of the last dose of study drug prior to this event) resulting in hospitalization. On Day 46, a cervical biopsy and cytology smear was performed and a pathologic diagnosis of cervical adenocarcinoma in situ was reported (last dose of study drug prior to this event was on Day 1). On Day 88, elective surgical excision of the entire cervix was performed with pathologic findings of intraepithelial adenocarcinoma in situ with no spread beyond the borders of the excised cervix and the event of cervical adenocarcinoma in situ was considered resolved. Approximately 10 years before this patient was enrolled in the study, she underwent a supravaginal hysterectomy for menorrhagia due to uterine fibromas and she had a normal Pap smear 3 years prior to the study. The investigator assessed the event of cervical adenocarcinoma in situ as serious and not related to the study drug but related to the concurrent illness. There was no change in the study drug due to the event of cervical adenocarcinoma in situ. She received a total of six doses of the study drug with the last dose administered on Day 138.

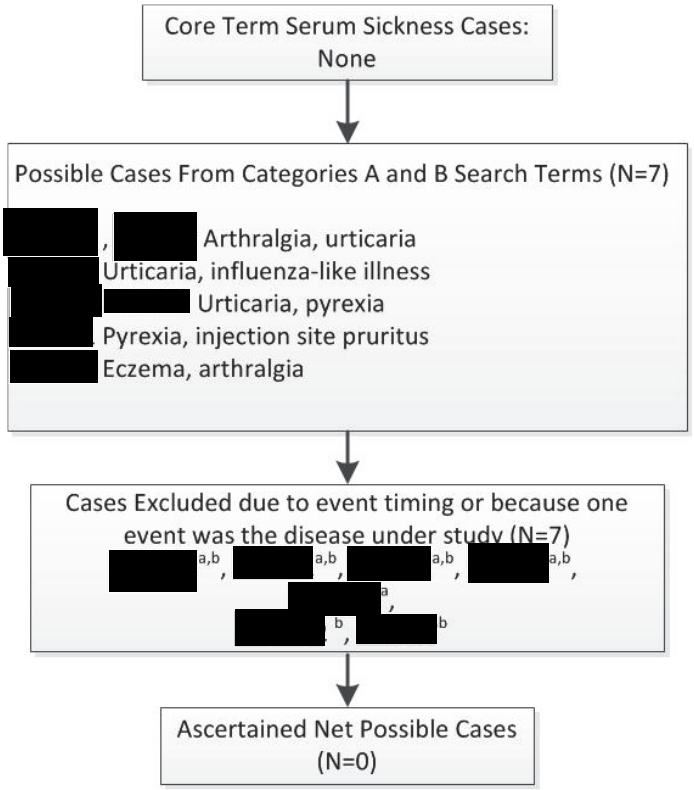
The narrative description for this patient can be found on page 187.

7.9.6 Serum Sickness Syndrome

There were no cases reported using the preferred term or verbatim term for serum sickness (see page 687).

AEs considered to be possible components of serum sickness syndrome which occurred during the treatment period were identified by preferred terms. AEs in Category A were defined by the high-level group term epidermal and dermal conditions and the high-level term urticarias. AEs in Category B were defined by the preferred terms influenza, arthralgia, pyrexia, and influenza like illness, and the high-level term skin vasculitides. Identified potential cases were evaluated by unblinded Sponsor clinical and safety scientists as possible components of serum sickness using the following criteria: the symptoms from Categories A and B were required to occur within 7 days of each other, and the Category A event was not urticaria. Seven possible cases were identified with use of the category criteria (2 patients [2.9%] in the omalizumab 75-mg group, 4 patients [4.6%] in the omalizumab 150-mg group, and 1 patient (1.2%) in the omalizumab 300-mg group) (see page 687), but all cases were excluded as a result of either event timing or the Category A event being the disease under study. This process is illustrated in Figure 11. A listing of Category A and B AEs considered possible components of serum sickness syndrome is also provided (see page 1131).

Figure 11 Flow Diagram for Serum Sickness Internal Adjudication Process



Category A = Epidermal and dermal conditions, urticarias; Category B = Influenza, arthralgia, pyrexia, influenza like illness, skin vasculitides.

[a] Events occurred at an interval exceeding 7 days.

[b] One of the Category A events was CIU, the disease under study.

Source: page 1131.

The two cases in which fluctuating CIU (the disease under study) was the reason for exclusion as serum sickness case by Sponsor clinician review are described below.

Patient [redacted] a [redacted]-year-old male randomized to omalizumab 75 mg, experienced severe idiopathic urticaria and mild influenza on Day 15 (14 days after receiving last dose of study drug prior to this event). The events of influenza and idiopathic urticaria resolved on Days 23 and 29, respectively. The investigators assessed these events as non-serious and not related to study drug. This patient also experienced severe influenza-like illness and severe urticaria (hives exacerbation) on Day 54 (25 days after receiving last dose of study drug). The event of influenza resolved the following day, and the event of urticaria resolved on Day 72. The investigators assessed these events as non-serious and not related to study drug (see page 1131). The study drug was permanently discontinued as a result of urticaria. The events of idiopathic urticaria and mild influenza occurred 14 days after receiving the last dose of study drug. After Sponsor unblinded clinical review, it was determined that these events were not a case of serum sickness caused by omalizumab as a result of both the prolonged time after

receipt of study drug and the variable intensity of the CIU skin symptoms of the disease under study. The changing condition of the skin symptoms (severe idiopathic urticaria event) is expected for CIU such that the additional event of influenza alone is insufficient to result in ascertainment of a true case of serum sickness.

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, experienced severe urticaria on Day 32 (2 days after the last dose of study drug prior to this event). On Day 36, she received treatment with prednisone for CIU and developed mild joint swelling, pain in extremity, and arthralgia, which were all considered resolved on the same day (Day 36). The investigators assessed these three events as non-serious and unrelated to study drug. On Day 37, the event of urticaria was considered resolved. The patient permanently discontinued study treatment due to the events of urticaria, joint swelling, pain in extremity and arthralgia on Day 36 (see page 1131). This patient developed mild arthralgia 6 days after receiving study drug but shortly after having received prednisone for urticaria; thus, this case is clinically unlikely to be serum sickness caused by omalizumab. In addition, the changing condition of the skin symptoms (severe urticaria event) is expected for CIU such that the additional events of mild joint swelling, pain in extremity, and arthralgia alone is insufficient to result in ascertainment of a true case of serum sickness.

Therefore, after application of the requirement for temporal association of events in Categories A and B, and because a cutaneous/urticaria event can be a result of the disease under study, no cases of serum sickness were identified.

The narrative description for Patients [redacted] and [redacted] can be found on page 187. A listing of AEs considered possible components of serum sickness syndrome is also provided (see page 1131).

7.9.7 Skin Rash Events

A search by the high-level terms erythemas, pruritus NEC, rashes, eruptions, and exanthems NEC identified 14 patients (4.4%) with possible skin rash: 5 patients (7.1%) in the omalizumab 75-mg group, 2 patients (2.3%) in the omalizumab 150-mg group, 3 patients (3.7%) in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group (see page 686, page 1134). All events were assessed by the investigator as not serious and not study drug related except for Patients [redacted] (omalizumab 150-mg group) and [redacted] (omalizumab 300-mg group) who were assessed by the investigator as not serious and related to study drug. These 2 patients are briefly described below.

Patient [redacted] (omalizumab 150-mg group) exhibited mild injection site pruritus on the day of the second study drug dose (Day 33). The event required no treatment and resolved on the same day (see page 1134).

Patient [redacted] (omalizumab 300-mg group) developed mild bilateral ankle itching on Day 77, 20 days after the prior dose of study drug (related). The pruritus was treated with topical mometasone (corticosteroid) (see page 1134).

7.9.8 Thrombocytopenia and Bleeding Related Disorders

A search for thrombocytopenia (SMQ thrombocytopenia search, subgroup of SMQ hematopoietic cytopenias) identified 1 patient (Patient [redacted] in the omalizumab 300-mg group considered a possible thrombocytopenia (see page 689, page 1136).

Patient [redacted] a [redacted]-year-old male randomized to omalizumab 300 mg, experienced mild thrombocytopenia on Day 29 (same day study drug administered). The event resolved on Day 57. The investigators assessed the event as non-serious and related to study drug (see page 1136). This patient had a single platelet count below the LLN of 129×10^9/L at the Week 4 visit (Day 29), with LLN of 140×10^9/L (see page 1137). The platelet counts at screening and Day 1 for this patient were 149×10^9/L and 196×10^9/L, respectively. On Day 57, platelet count increased to 144×10^9/L and the event of thrombocytopenia was considered resolved. The range of platelet count values from Week 8 to Week 40 was 144×10^9–175×10^9/L with no overall trend in the values observed during the entire study including the screening period (pre-randomization) values. This patient was not discontinued from study drug as a result of thrombocytopenia (see page 1136 and page 1108).

In addition to reviewing reported AEs of thrombocytopenia identified by the prespecified SMQ searches, the platelets counts collected as part of the hematology panel were reviewed to identify potential cases of thrombocytopenia by applying the following criteria: a platelet count $< 75 \times 10^9$/L or a $\geq 50\%$ reduction from baseline in platelet count. The results of the review of platelet counts are detailed in Section 7.11.1.

A search for hemorrhages (SMQ hemorrhages search) identified 10 patients (3.1%) considered possible bleeding related events: 2 patients (2.9%) in the omalizumab 75-mg group, 1 patient (1.1%) in the omalizumab 150-mg group, 5 patients (6.2%) in the omalizumab 300-mg group, and 2 patients (2.5%) in the placebo group (see page 689). There was a higher incidence of possible bleeding related events in the omalizumab 300-mg group than in the placebo group. The bleeding events by preferred term were: ecchymosis (1 patient [1.4%] in the omalizumab 75-mg group and 1 patient [1.2%] in the omalizumab 300-mg group), menorrhagia (1 patient [1.1%] in the omalizumab 150-mg group and 1 patient [1.2%] in the omalizumab 300-mg group), contusion (1 patient [1.3%] in the placebo group), gingival bleeding (1 patient [1.3%] in the placebo group), haematochezia (1 patient [1.4%] in the omalizumab 75-mg group), haemoglobin decreased (1 patient [1.2%] in the omalizumab 300-mg group), haemorrhagic anaemia (1 patient [1.4%] in the omalizumab 75-mg group), injection site haemorrhage (1 patient [1.2%] in the omalizumab 300-mg group), and rectal haemorrhage (1 patient [1.2%] in the omalizumab 300-mg group).

All bleeding events were assessed as mild or moderate in intensity, non-serious, and considered resolved (see page 1241). Regarding concurrent medications that might cause bleeding, 5 of the 10 patients were taking NSAIDs at the time of the event:

- Patient [redacted] (75 mg omalizumab, preferred term ecchymosis): ibuprofen 200 mg, when necessary
- Patient [redacted] (300 mg omalizumab, preferred term injection site hemorrhage): naproxen 220 mg, when necessary
- Patient [redacted] (300 mg omalizumab, preferred term haemoglobin decrease): ibuprofen 200 mg, when necessary
- Patient [redacted] (300 mg omalizumab, preferred term menorrhagia): ibuprofen 1 tab twice a day
- Patient [redacted] (placebo, preferred term gingival bleeding): acetaminophen, aspirin, caffeine 2 tablets/day.

None of the patients were taking other agents with known anticoagulant or bleeding properties. None of the patients with possible bleeding related events who received omalizumab exhibited low platelet counts at any time in the study (see page 1137). All of the bleeding related events were assessed as not related to the study drug except for one (Patient [redacted] . One event of injection site haemorrhage (Day 1) was reported in Patient [redacted] (omalizumab 300-mg group). The event was reported as moderate in intensity and the investigators assessed the event as related to study drug. No treatment was required and there was no change to study drug. (see page 1241).

There were no study drug discontinuations as the result of a bleeding-related event. A listing of bleeding related events has been provided on page 1241.

7.9.9 Hematopoietic Cytopenias

A broad search for hematopoietic cytopenias (SMQ hematopoietic cytopenias search) identified 5 patients (1.6%) considered to have possible hematopoietic cytopenias: 2 patients (2.3%) in the omalizumab 150-mg group, and 3 patients (3.7%) in the omalizumab 300-mg group (see page 690, page 1243). There was a higher incidence of possible hematopoietic cytopenias in the omalizumab 300-mg group than in the placebo group. The hematopoietic cytopenias by preferred term were: anaemia, haemoglobin decreased, neutropenia, thrombocytopenia, and white blood cell count decreased.

The hematopoietic cytopenia events resolved in 3 out of the 5 patients (Patients [redacted], [redacted] [redacted]) while the events were ongoing in the remaining 2 patients (Patients [redacted] and [redacted]) when they completed the study. All hematopoietic cytopenia events were reported to be mild or moderate and non-serious; only one event of thrombocytopenia in Patient [redacted] was assessed by the investigators as related to study drug (see page 1243). For more details on Patient [redacted] see Section 7.9.8. Two cases (Patients [redacted] and [redacted] were events of mild anemia that did not require treatment. One case (Patient [redacted]) exhibited a single value for absolute neutropenia

of $1.28 \times 10^3/\mu L$ (LLN $= 1.50 \times 10^3/\mu L$) that was attributed to a reaction to a concomitant medication (see page 1137). The final case (Patient [redacted]) had a decrease in white blood cell (WBC) counts that was attributed to a concomitant illness. In this case the nadir WBC occurred at Week 20 with a value of $2.68 \times 10^3/\mu L$ (LLN $= 2.0 \times 10^3/\mu L$) which is within normal limits, and all other screening and treatment WBC values were within normal limits.

7.9.10 Arterial Thrombotic Events

As part of the search for SMQs to identify ATEs, a broad search for cardiac ischaemic events identified 1 patient (Patient 14301) in the omalizumab 150-mg group (see page 691, page 1244, page 1245).

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, experienced a severe unstable angina on Day 148 (last dose of study drug prior to this event was on Day 141), which resolved in Day 152. The patient had a medical history of severe ischemic heart disease. The investigators assessed the event as serious and not related to the study drug and related to concurrent illness. The patient permanently discontinued study as a result of the unstable angina. (see page 1244 and page 1108). For more details see Section 7.6.4.

The narrative description for Patient [redacted] can be found on page 204.

7.9.11 Asthma/Bronchospasm Events

A search for asthma/bronchospasm (SMQ asthma/bronchospasm search) identified 13 patients (4.1%) considered to have possible asthma/bronchospasm events: 2 patients (2.9%) in the omalizumab 75-mg group, 5 patients (5.7%) in the omalizumab 150-mg group, 2 patients (2.5%) in the omalizumab 300-mg group, and 4 patients (5.0%) in the placebo group (see page 692). All patients identified by this SMQ asthma/bronchospasm search had a history of asthma/bronchospasm at baseline, except Patients [redacted] and [redacted] which are briefly described below. In addition, a brief description of Patient 12302 is provided since this patient was discontinued from study drug as a result of the asthma exacerbation.

Patient [redacted] a [redacted]-year-old female randomized to omalizumab 75 mg, developed a cough on Day 175 and was treated with a salbutamol inhaler. On the next day (Day 176), the patient experienced mild wheezing. By Day 196, the medication was changed to a salmeterol/fluticasone inhaler. By Day 276, bronchitis was diagnosed and erythromycin added to the treatment regimen (see page 1246 and page 1058). At enrollment, this patient had food and latex allergies.

Patient [redacted] a [redacted] year-old female randomized to omalizumab 150 mg, did not have a history of asthma and allergic rhinitis. She was diagnosed with an upper respiratory infection on Day 29 followed by wheezing on Day 39 and received treatment with salbutamolinhaler and a course of azithromycin (see page 1246 and page 1058).

Patient [redacted] a [redacted] year-old female (with history of asthma) randomized to placebo, experienced a toxic chemical exposure (unstated chemical species) that resulted in a mild exacerbation of preexisting asthma on Day 139 (last dose of study drug prior to this event was on Day 119). On Day 139, she was treated with prednisolone, levosalbutamol hydrochloride/levosalbutamol tartrate and budesonide. On Day 141, the event of exacerbation of preexisting asthma was considered resolved. On Day 143, the patient was diagnosed with streptococcal pharyngitis and treated with azithromycin. On Day 169, the event of streptococcal pharyngitis was considered resolved. On Day 148, the patient was discontinued from study drug due to the asthma exacerbation. The investigators assessed the event of asthma exacerbation as non-serious and not related to the study drug (see page 1246).

The narrative description for Patient [redacted] can be found on page 210.

7.9.12 Liver-Related Investigations, Signs and Symptoms

No possible liver-related events were reported using a search for liver-related investigations, signs and symptoms (SMQ Liver-related investigations, signs and symptoms search) (see page 693, page 1249). No liver enzyme or bilirubin testing was performed post-baseline as part of the study.

7.10 PREGNANCIES

There were three pregnancies reported in this study (see page 1250).

- Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, received 6 doses of study drug with the last dose administered on Day 138, and was found to be pregnant on an unspecified date of 2012. For more details see Section 7.6.4.
- Patient [redacted] a [redacted]-year-old female randomized to omalizumab 150 mg, received 6 doses of study drug with the last dose administered on Day 141. On Day 281, the patient was found to be pregnant (gestational age not provided), and her last menstrual period date was reported on Day 269. Her conception date was unknown, and her estimated date of delivery was Day 549. The patient completed the study follow-up visit on Day 281. The outcome of the event of pregnancy was reported as ongoing at the last day of study follow-up.
- Patient [redacted] a [redacted]-year-old female randomized to placebo, received 6 doses of study drug with the last dose administered on Day 141. On Day 281, an unspecified pregnancy test was positive (gestational age not provided). It was reported that exposure of study drug was at Week 1. The patient completed the study follow-up visit on Day 289. The patient's estimated date of delivery was Day 526. The outcome of the event of pregnancy was reported as ongoing at the last day of study follow-up.

The narrative descriptions for Patients [redacted] [redacted] and [redacted] can be found on page 187.

7.11 LABORATORY PARAMETERS

7.11.1 Hematology

For all hematology lab parameters, no notable changes or major differences across treatment groups were observed in the values assessed by visit and change from baseline (see page 694). Mean platelet count changes from baseline were small in all groups. By Week 24, the largest change in mean platelet count from baseline (-5.4×10^9/L in the omalizumab 300-mg group) with the baseline value of 295.97×10^9/L and a Week 24 value of 290.56×10^9/L (see page 694).

Based on additional analyses that defined a clinically significant decrease as a platelet count $< 75 \times 10^9$/L or a $\geq 50\%$ reduction from baseline, Patient [redacted] (omalizumab 150-mg group) met both criteria (see page 1251). For this patient, the platelet count reduction was an isolated event. The baseline value was 244×10^9/L with the single platelet count reduction to 67×10^9/L (a 72.5% decrease), occurring at Week 12 ([redacted]). Since this value was outside the normal range, the investigator decided to repeat the platelet count a few days later ([redacted]) and the result of this re-test was normal (219×10^9/L). In addition, this patient's platelet count was also normal at Week 8 (218×10^9/L) and Week 16 (222×10^9/L). This patient was not discontinued from study drug as a result of this laboratory result.

Shifts from baseline by visit for the hematology tests performed are presented on page 724. The study had few clinically significant abnormal hematology values. There were 6 patients who exhibited an increase in WBC count at Week 24: 2 patients in the omalizumab 75-mg group, 1 patient in the omalizumab 300-mg group, and 3 patients in the placebo group (see page 724 and page 1137). Patient [redacted], in the placebo group, exhibited an increase in WBC count up to 21.34×10^9/L at Week 24. This increase in WBC count was in association with a sinus infection that required treatment (see page 1137 and page 1058). Patient [redacted] in the omalizumab 300-mg group, exhibited a single increase in WBC count up to 23.01×10^9/L at Week 32. This increase in WBC count was attributed to a concomitant illness and the investigator assessed the increase as mild (see page 1137 and page 1058).

There were 5 patients who developed subnormal hematocrit values at Week 24 following normal values at baseline: 1 patient in the omalizumab 75-mg group, 1 patient in the omalizumab 150-mg group, 2 patients in the omalizumab 300-mg group, and 1 patient in the placebo group (see page 724 and page 1137). By Week 40, there were 4 patients with subnormal hematocrit values: 1 patient in the omalizumab 75-mg group, 2 patients in the omalizumab 150-mg group, and 1 patient in the omalizumab 300-mg group.

There was a shift from normal at baseline to below the LLN (140×10^9/L) for platelet count in 9 patients during the treatment or follow-up period: 2 patients in the omalizumab 150-mg group (Patients [redacted] and [redacted]), 6 patients in the omalizumab 300-mg group (Patients [redacted], and [redacted]), and 1 patient

in the placebo group (Patient [redacted]) (see Table 40). During the treatment period there were 8 patients with a shift from normal at baseline to below the LLN range for platelet count: 2 patients in the omalizumab 150-mg group, 5 patients in the omalizumab 300-mg group, and 1 patient in the placebo group (see Table 40). During the follow-up period there were 2 patients with a shift from normal at baseline to below the LLN range for platelet count, both in the omalizumab 300-mg group. By Week 40, the decrease in platelet count normalized in each patient in the omalizumab groups, except Patient [redacted] who discontinued from the study as a result of unstable angina on Day 169, and at this time this patient's platelet count had normalized to 311×10^9/L. For more details on Patient [redacted] see Section 7.6.4. Thus, in all cases, shift from normal at baseline to below the LLN range for platelet count was transient. No bleeding events were associated with the platelet count depressions observed in the patients assigned to the omalizumab groups, and these values were not considered clinically significant decreases, except for Patient [redacted] (described above). In addition to the patients with a shift from normal at baseline to below the LLN range for platelet counts, Patient [redacted] had a low platelet count at baseline, Weeks 4, 8, and 12, and at early termination (see page 1137). Patient [redacted] discontinued the study as a result of the patient/legal guardian decision to withdraw on Day 113 (see page 871), and at early termination this patient's platelet count was 104×10^9/L, similar to the values of 108×10^9/L and 79×10^9/L that were present at screening and baseline, respectively. The nadir platelet count for Patient [redacted] was 78×10^9/L at Week 3.

Table 40 Shift from Normal at Baseline to Below the LLN (140×10^9/L) for Platelet Count during the Treatment and Follow-up Periods: Safety Evaluable Patients

Visit	Placebo	Omalizumab 75 mg	Omalizumab 150 mg	Omalizumab 300 mg
Week 4	1 (1.4%)	0	0	2 (2.7%)
Week 8	0	0	0	1 (1.4%)
Week 12	0	0	1 (1.3%)	1 (1.4%)
Week 16	0	0	1 (1.4%)	1 (1.4%)
Week 20	1 (1.8%)	0	0	3 (4.2%)
Week 24	0	0	0	1 (1.4%)
Week 32	0	0	0	2 (3.1%)
Week 40	0	0	0	0

Note: Percentages are based on the number of observations; consequently, the denominators may vary.

Source: page 724, page 1137.

7.11.2 Chemistry

Serum chemistry values were measured at screening (Day −14) only and included sodium, potassium, chloride, random glucose, albumin, aspartate transaminase (AST), and alanine aminotransferase (ALT) values (see page 862). Serum glucose levels were random relative to carbohydrate intake.

7.11.3 Urinalysis

Urinalysis including microscopy was performed at screening (Day −14) only (see page 863). Urine protein analysis by dipstick was normal (negative or trace) in 298 patients and exceeded trace magnitude in 17 patients. Three patients experienced greater than trace urine glucose. Urinary ketone and specific gravity results were also consistent with a normal population containing few patients with diabetes. With respect to urinary microscopy results, 5 patients exceeded 5 red blood cells [RBC]/high power field [HPF]). In addition, 7 patients exceeded 20 WBC/HPF.

7.12 OTHER SAFETY TESTS

7.12.1 Vital Signs

A listing of vital signs (pulse rate and blood pressure) is presented on page 1252. No treatment-emergent changes in systolic blood pressure (SBP), DBP, or pulse were noted in any treatment groups.

7.12.2 Immunogenicity

ATA results are summarized on page 864 and page 1366. For details on the ATA assay and sample analysis methods see the bioanalytical report on page 2513 .

ATAs were measured at Day 1 (predose) and Week 40 (end of follow-up period).
No ATA response was detected in any patient at any timepoint throughout the study (see page 864).

8. DISCUSSION

Study Q4881g met its primary efficacy endpoint by demonstrating statistically and clinically significant decreases from baseline in weekly itch severity scores at Week 12 in patients in the omalizumab 75-mg, 150-mg, and 300-mg groups relative to the placebo group: -6.46 ($p=0.0010$), -6.66 ($p=0.0012$), and -9.40 ($p<0.0001$) versus -3.63, respectively. In addition, the following endpoints were met in the study by demonstrating statistically significant improvements in patients in the omalizumab groups (as specified) compared with patients in the placebo group: all 9 secondary efficacy endpoints for the 300-mg omalizumab group; the first six secondary efficacy endpoints for the 150-mg omalizumab groups; the first two secondary efficacy endpoints for the 75-mg omalizumab group.

The robustness of the primary efficacy results was supported by consistent findings from the sensitivity and subgroup analyses. For the primary efficacy endpoint, missing Week 12 weekly itch severity scores were imputed by carrying forward the baseline weekly itch severity score (BOCF), and thus imputing no change from baseline.
The sensitivity analyses performed on the primary endpoint with use of the LOCF method to impute the missing Week 12 scores and fitting a longitudinal mixed effects model on observed data produced similar results to those of the primary analysis with use of the BOCF method for imputation of missing Week 12 scores. In addition, across the examined subgroups for all three omalizumab doses, the treatment effects of omalizumab versus placebo were generally consistent with the overall primary analysis results.

The discontinuation rate from study treatment in the placebo group was double the rate in the omalizumab 300-mg group, and as expected the most common reasons for study drug treatment discontinuation were disease progression and AEs which are consistent with the underlying disease. Given the consistent results from the sensitivity analyses performed, the imbalance in treatment discontinuation rates between the placebo group and 300 mg omalizumab group, does not impact the overall results or conclusions from the efficacy analyses.

The patient population in this study had balanced baseline characteristics across all treatment groups. At baseline, patients had an average UAS7 of 31.1, were symptomatic despite treatment with H1 antihistamine, had an average duration of CIU

of 6.9 years (median 3.7 years), and were treated for their CIU with 4.7 previous medications on average. A high percentage of patients reported angioedema at baseline (47.5%), and the IgE levels of the study population as a whole were also elevated (mean total IgE 182.8 IU/mL; median 83.0 IU/mL); however, this was not as high as observed in the asthma population (Bousquet et al. 2011). At screening, patients generally appeared to have normal serum chemistry, glucose, and urinalysis results.

Patients in the omalizumab 75-mg, 150-mg, and 300-mg groups showed improvement in their CIU symptoms as demonstrated by statistically significant decreases in weekly itch severity score, UAS7, and weekly number of hives score at Week 12, compared with placebo. A statistically significant rapid onset of treatment effect in the omalizumab150-mg and 300-mg groups compared with placebo was observed as measured by time to MID response. In addition, for the omalizumab 300-mg group, improved quality-of-life was demonstrated by a statistically significant difference compared with placebo in the change from baseline in overall DLQI at Week 12, mean proportion of angioedema-free days from Week 4 to Week 12, and proportion of complete responders at Week 12. After Week 24, the mean symptom scores for the three omalizumab dose groups increased gradually to values similar to the mean values for the placebo group and neither the placebo group nor any of the omalizumab groups returned to the mean baseline values.

A dose response was observed across the primary and secondary efficacy endpoints. For all the secondary efficacy endpoints, the 300-mg omalizumab group demonstrated the greatest efficacy relative to the placebo group at the Week 12 followed by the omalizumab 150-mg dose group and the omalizumab 75-mg dose group. In addition, the results of the analyses of the exploratory endpoints were consistent with the results from the primary and secondary analyses endpoints with respect to the omalizumab treatment effect in all three doses. In general, the results of the analyses consistently favored the omalizumab 300-mg group compared to the placebo group.

The results of the analysis of the exploratory endpoints at Week 24 were generally consistent with the results from Week 12 demonstrating that the efficacy observed at week 12 was maintained to Week 24. For the outcomes measuring change from baseline to Week 24 in weekly itch severity score, UAS7, weekly number of hives score, and weekly size of largest hive score, the magnitudes of the mean changes from baseline in the omalizumab dose groups were similar to the corresponding magnitudes of the changes from baseline to Week 12. Furthermore, the efficacy response observed at Week 12 was maintained to Week 24 since the proportion of patients with UAS7 ≤ 6 at Week 24 and Week 12 were generally consistent and the proportions of patients with complete response (UAS7 $= 0$) increased from Week 12 to Week 24 for all treatment groups.

Following SC administration of omalizumab 75 mg, 150 mg, or 300 mg every 4 weeks, mean serum omalizumab concentrations at Week 12 and Week 24 increased proportionally with dose level. The concentrations at Week 24 were similar to those at Week 12 in patients for each dose group, suggesting that steady state was approached by Week 12. Mean serum free IgE levels were suppressed dose dependently from baseline to Week 12, remained stable from Week 12 to Week 24, and recovered toward baseline by the end of the follow-up period. Mean serum total IgE levels increased 2- to 3-fold from baseline to Week 12, remained stable from Week 12 to Week 24, and returned close to baseline levels by the end of the follow-up period.

The incidence of common treatment-emergent AEs during the treatment period was higher in the omalizumab group (57 to 69%) than the placebo group (51%), and the majority of these events were mild or moderate in intensity. The event types, during the treatment period, that account primarily for the higher AE rate in the omalizumab groups were headaches, arthralgia and injection-site reactions, which are events known to occur with omalizumab use in patients with moderate to severe asthma.

During the follow-up period, the incidence of treatment-emergent AEs were higher in the omalizumab group (47% to 52%) than the placebo group (40%). Skin and subcutaneous disorders was one of the most commonly affected SOCs for which a greater frequency of AEs was observed in the omalizumab groups than the placebo group. The most commonly reported event by preferred term were idiopathic urticaria (8.2% of patients), with the highest incidence of events reported in the omalizumab 300-mg group. The higher frequency of AEs observed in the omalizumab groups during the follow-up period appear to be explained in part by skin-related AEs, urticaria in particular (consistent with the underlying disease).

The proportions of patients experiencing at least one AE suspected to be caused by study drug increased with increasing omalizumab dose, with the lowest proportion of patients in the placebo group and the highest in the omalizumab 300-mg group. The majority of these AEs were mild or moderate in intensity. The dose-dependent trend in AEs suspected to be caused by study drug could not be attributed to any single type of AE, but was observed across multiple SOCs. The largest numerical differences between omalizumab and placebo groups were observed for headache and injection-site reactions.

While on study, the proportion of patients with reported treatment-emergent SAEs was low overall (4.4% of all patients), and was numerically lower in the omalizumab groups (2.5% to 5.7%) compared to placebo (6.3%). A similar pattern was observed for SAEs occurring during the treatment period. None of the reported SAEs were assessed by the investigator as related to study drug. Types of SAEs were distributed across various different preferred terms. Consistent with all AEs, severe skin and subcutaneous disorders was the most commonly affected SOC; however, the frequency of severe AEs

within this SOC was not consistently higher in the omalizumab groups compared with placebo.

Possible bleeding related events and possible hematopoietic cytopenias were the most notable increase in the incidence of AEs of special interest in patients in the omalizumab 300-mg group compared with patients in the placebo group. The bleeding related events were all mild to moderate in intensity, non-serious, and were not associated with a decrease in platelet counts. All the hematopoietic cytopenia events were mild to moderate in intensity and non-serious.

Three events were identified by the Sponsor as suspected cases of anaphylaxis and submitted for blinded, external adjudication. Two of the three suspected cases were externally adjudicated as anaphylaxis. One case (Patient [redacted] was determined to be unrelated to study drug, and one (Patient [redacted] case was initially determined to be related to study drug; however, after receipt of additional information regarding the timing of study drug administration, the Anaphylaxis Review Committee re-assessed Patient [redacted] as a case of anaphylaxis not related to study drug.

The case of anaphylaxis determined to be unrelated to study drug occurred during the follow-up period on Day 283 (142 days after the receipt of the final dose of study drug). The patient developed an anaphylactic reaction 30 minutes after being re-challenged with dipyrone for pain relief. The Anaphylaxis Review Committee determined that this event was an event of anaphylactic reaction not related to study drug but related to dipyrone. Numerous case reports of severe anaphylaxis following intraoperative IV dipyrone have been published (Eckle et al. 2005). Rigorous pharmacovigilance methods have corroborated the significant anaphylaxis risk of dipyrone (Leone et al. 2005).

The case of anaphylaxis determined to be related to study drug was reported by the investigator as an exacerbation of urticaria. In addition to urticaria, the patient also reported gastrointestinal symptoms including abdominal cramps and diarrhea. The combination of these symptoms within 1 day of last (6^{th}) dose of study drug met the criteria for anaphylaxis. However, the time of the last dose of study drug and the urticaria event and gastrointestinal symptoms was approximately 15 hours with no changes in vital signs. (For further details on this anaphylaxis case, please see Section 7.6.4 and 7.9.1.) Although gastrointestinal symptoms have been reported in approximately 17%-29% of cases of anaphylaxis (Wong et al. 1990; Brown 2004; Webb et al. 2006), gastrointestinal symptoms are also a common complaint among patients with chronic urticaria.

Transient decreases in platelets were observed in a small minority of patients (8 of 238 patients assigned to the omalizumab groups). One of these patients met the criteria for clinically significant thrombocytopenia defined as $>50\%$ reduction in platelet counts from baseline or $<75\times10^{9}$/L platelet count ; however, the platelet count value spontaneously returned to normal upon retesting a few days later. No bleeding events

were associated with platelet count depressions observed in patients assigned to the omalizumab groups. Furthermore, from the hematology data, there does not appear to be a relationship between the omalizumab dose and a WBC increase or the occurrence of anemia.

In summary, these study findings suggest that omalizumab is efficacious for the treatment of CIU in patients who remain symptomatic despite treatment with antihistamines. This conclusion is supported by statistically significant changes in the primary endpoint of weekly itch severity score, as well as by observed improvements in multiple other secondary endpoints. Overall, omalizumab was well tolerated and demonstrated a safety profile that was similar to what has been previously reported among patients with allergic asthma. Taken together, these findings suggest that omalizumab offers a favorable benefit-risk profile for patients with refractory CIU.

9. OVERALL CONCLUSIONS

Omalizumab therapy in adolescent and adult patients aged 12–75 years with refractory CIU receiving concomitant approved doses of H1 antihistamine in this global, Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study demonstrated significant clinical benefits and no new safety concerns as supported by the following conclusions:

- Statistically significant effects conferring therapeutic benefits were observed in the omalizumab 75-mg, 150-mg, and 300-mg groups for the primary efficacy endpoint.
- All nine secondary efficacy endpoints were met in the omalizumab 300-mg group compared with the placebo group. The first six secondary efficacy endpoints were met in the omalizumab 150-mg group compared with the placebo. The first two secondary efficacy endpoints were met in the omalizumab 75-mg group compared with the placebo group.
- The robustness of the primary efficacy results was supported by consistent findings from the sensitivity and subgroup analyses.
- Patients in the omalizumab groups had a rapid onset of treatment effect, and after Week 24 (follow-up period), mean symptom scores increased to reach values similar to mean placebo group values and neither the placebo group nor any of the omalizumab groups returned to the baseline values for the duration of the follow-up period.
- A dose response was observed with the efficacy results. For all the secondary efficacy endpoints, the 300-mg omalizumab group demonstrated the greatest efficacy relative to the placebo group at Week 12.
- Compared to the placebo group, a statistically significant improvement in health-related quality of life was observed for patients in the omalizumab 300-mg group as reflected by a greater decrease from baseline in overall DLQI score.

- The difference between the omalizumab 300-mg and the placebo groups in mean proportion of angioedema-free days from Week 4 to Week 12 was statistically significant in favor of omalizumab ($p < 0.0001$).
- The incidence of common treatment-emergent AEs during the treatment period was higher in the omalizumab group (57 to 69%) than the placebo group (51%) and the majority of these events were mild or moderate in intensity. During the treatment period, the event types that account for the higher AE rate in the omalizumab groups were events known to occur with omalizumab use in patients with moderate to severe asthma.
- While on study, the overall proportion of patients with reported treatment-emergent SAEs was 4.4% of all patients, and the SAE rate was numerically lower in the omalizumab groups than in the placebo group. No deaths occurred.
- Three suspected cases of anaphylaxis were identified by the Sponsor and submitted for blinded, external adjudication. Two cases were adjudicated as an anaphylaxis event not related to study drug and one case was adjudicated as not an anaphylaxis event.
- Omalizumab was generally well tolerated and did not result in new or clinically significant safety concerns in patients with refractory CIU. The AEs were consistent either with the known omalizumab safety profile in allergic asthma patients or with those CIU-related events observed in the placebo group of this study.

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1. NARRATIVES

1.1 NARRATIVES FOR SUBJECTS WHO DIED DUE TO AN ADVERSE EVENT

No subject died due to an adverse event during this study.

1.2 NARRATIVES FOR SUBJECTS WHO EXPERIENCED A SERIOUS ADVERSE EVENT

1.2.1 Narratives for subjects in the Placebo arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: adenocarcinoma in situ, cervix
MedDRA Preferred Term: Cervix carcinoma stage 0

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 8 years and 1 month prior to her study start and had prior treatment with cetirizine, acrivastine, ranitidine, ciclosporin, mycophenolate mofetil, azathioprine and adalimumab for CIU. The subject's concomitant CIU medication was fexofenadine

On [redacted] she underwent a supravaginal hysterectomy for menorrhagia due to uterine fibromas. The cervix was not excised. A normal Pap smear was reported 3 years prior to study. No other concomitant medications were reported.

On [redacted], her baseline hematological tests were normal.

The last dose of study drug prior to the event of cervical adenocarcinoma in situ was administered on [redacted] (study day 1).

On [redacted] (study day 10), nine days after the receipt of the last dose of study drug, a routine smear was taken from the cervix (reason not specified) and the subject was diagnosed with severe cervical dysplasia (assessed as serious; unrelated to the study drug) resulting in hospitalization. On [redacted] (study day 46), a cervical biopsy and cytology smear was performed and a pathologic diagnosis of cervical adenocarcinoma in situ was reported.. On [redacted] (study day 88), elective surgical excision of the entire cervix was performed with pathologic findings of intraepithelial adenocarcinoma in situ

with no spread beyond the borders of the excised cervix and the event of cervical adenocarcinoma in situ was considered resolved.

The investigator assessed the event of cervical adenocarcinoma in situ as serious and not related to the study drug but related to the concurrent illness.

There was no change in the study drug due to the event of cervical adenocarcinoma in situ. She received a total of six doses of the study drug with the last dose administered on [redacted] (study day 138).

The subject completed the study follow-up visit on [redacted] (study day 281).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Distal radius extension fracture-left
MedDRA Preferred Term: Radius fracture

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol or [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 17 years and 3 months prior to his study start and had prior treatment with ranitidine, ebastine, cetirizine, loratadine and montelukast sodium for CIU. The subject's concomitant CIU medication was fexofenadine.

His concurrent condition included reflux. Concomitantly, he was receiving pantoprazole sodium, dipyrone and ibuprofen, for conditions other than CIU.

On [redacted] his baseline hematological laboratory tests were normal except for low absolute lymphocyte count 0.84 × 10^3/µL (normal range: 0.91-4.28× 10^3/µL) and high segmented neutrophils percent 76.5% (normal range: 40.5-75%).

The last dose of study drug prior to the event of radius fracture was administered on [redacted] (study day 29).

On [redacted] (study day 41), 12 days after the receipt of the last dose of study drug, the subject slipped and had a fall while taking shower. He added that he did not feel dizzy. He was diagnosed with severe distal radius extension fracture-left (radius fracture) (assessed as serious; unrelated to the study drug) resulting in hospitalization for internal fixation of the fracture. On [redacted] (study day 135), he received treatment with

atropine, etomidate, piritramide, remifentanil, dexamethasone and propofol during out-patient surgery to remove the metal plate fixation device. The fracture was completely healed and the subject was in good condition. The same day (study day 135), the event of radius fracture was considered resolved.

The investigator assessed the event of radius fracture as serious and not related to the study drug but related to other: concomitant medication.

There was no change in the study drug due to the event of radius fracture. He received a total of six doses of the study drug with the last dose administered on [redacted] (study day 144).

The subject discontinued from the study and did not complete the follow up period as a result of disease progression on [redacted] (study day 177).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Exacerbation of COPD
MedDRA Preferred Term: Chronic obstructive pulmonary disease

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 3 years and 3 months prior to her study start. The subject's concomitant CIU medication was rupatadine.

She had history of [redacted]. Her concurrent conditions included hypertension, chronic obstructive pulmonary disease, osteopenia, angioedema (since [redacted]) and asthma. Concomitantly, she was receiving amlodipine, fluticasone propionate/salmeterol xinafoate, tiotropium bromide and salbutamol/salbutamol sulfate, for conditions other than CIU.

On [redacted], her baseline hematological tests were normal.

The last dose of study drug prior to the event of exacerbated chronic obstructive pulmonary disease was administered on [redacted] (study day 30).

On [redacted] (study day 55), 25 days after the receipt of the second dose of study drug, the subject was hospitalized due to severe flu-like infection with fever, dyspnea and developed bronchitis. She was diagnosed with severe exacerbation of chronic obstructive pulmonary disease by infection (chronic obstructive pulmonary disease), assessed as

serious; unrelated to the study drug. It was reported that the subject received hydrocortisone from her family doctor as a short infusion at around 9:00 pm. The subject had vomited once and she developed increasing dyspnea. On physical examination, the subject was in reduced general condition, blood pressure at 160/80 mmHg, temperature at 38.6ºC, pulse at 127 bpm, oxygen saturation at 75% under room air, conscious and oriented on admission, no peripheral edema was observed. Chest was hypersonorous to percussion, ubiquitous rhonchi were present more on right than left. Chest X-ray showed pulmonary emphysema with narrow heart in central position as well as distinctly over-expanded lungs with flat diaphragms. No evidence of cardiac failure, pleural effusion or infiltrates was seen. Electrocardiogram showed sinus tachycardia (127 bpm), normal R-wave progression and no repolarization dysfunction. No focal neurological deficit, abdominal tenderness or area of resistance was observed. On [redacted] (study day 56), a pulmonary function testing showed vital capacity 1.48 L, FEV1 0.59 L, FEV1/vital capacity 40%, peak expiratory flow 1.30 L/s. On the same day, echocardiography showed good LV function with no evidence of relevant valve defects, somewhat enlarged right heart, slight tricuspid valve regurgitation and systolic pressure in the minor circulation was 60-70 mmHg. She was treated with amoxicillin/clavulanate potassium and clarithromycin. Over the hospital course, the symptoms improved distinctly after nine days of antibiotic therapy. Furthermore, the subject received oral prednisone (Decortin), which was tapered. Under prednisone therapy, there was an oral Candida infestation, which was treated with local amphotericin B for three days. She also received treatment with tiotropium bromide, amoxicillin/clavulanate potassium, clarithromycin and metoclopramide. On [redacted] (study day 64), the event of exacerbated chronic obstructive pulmonary disease was considered resolved and the subject was discharged in an improved general condition.

The investigator assessed the event of exacerbated chronic obstructive pulmonary disease as serious and not related to the study drug but related to the concurrent illness, infection and smoking.

The study drug was permanently discontinued as a result of chronic obstructive pulmonary disease. She received a total of two doses of the study drug with the last dose administered on [redacted] (study day 30).

The subject completed the study follow-up visit on [redacted] (study day 231).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Diabetes 2
MedDRA Preferred Term: Type 2 diabetes mellitus

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], in a phase III multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 3 years and 10 months prior to his study start. The subject's concomitant CIU medication was levocetirizine. The subject had previously taken long term PO prednisolone for CIU and had gained 20 kg during a recent 1 year interval on that agent, which had been discontinued for the past year.

His medical history included [redacted]. His concurrent conditions included "pytiriasis versicolor", [redacted] allergy, [redacted] allergy, obesity, hypercholesterolemia and hypertension. His grandmother had Type 2 diabetes. Concomitantly, he was receiving telmisartan and rosuvastatin, for conditions other than CIU.

At screening, the subject had high blood glucose at 189 mg/dL (normal range: 69.8-99.9 mg/dL).

On [redacted], his baseline hematological laboratory tests were normal. Starting at approximately [redacted] the subject noted polydipsia and polyuria associated with a 4 kg weight loss through [redacted] (study day 31).

The last dose of study drug prior to the event of Type 2 diabetes mellitus was administered on [redacted] (study day 29).

On [redacted] (study day 29), on the day when the subject received second dose of study drug, he experienced moderate hyperglycemia (non-serious, unrelated; blood glucose value not provided). On [redacted] (study day 31), two days after the receipt of the last dose of study drug, the subject was hospitalized due to severe Type 2 diabetes mellitus (assessed serious; unrelated to the study drug) induced by corticosteroid therapy. His blood glucose was 2.65 g/L or 265 mg/dL (3.02 g/L or 302 mg/dL in the emergency room), blood pressure was 140/70 mmHg, pulse was 70/minute, body temperature was 37ºC, body weight 121.4 kg, BMI 38, he was conscious with clear bilateral vesicular breath sounds. It was also reported that the abdomen was in "plethoric and supple state" with reduced bowel sounds, no constipation and no burning sensation on urination. On same day, laboratory tests showed hemoglobin 15.6 g/dL, mean cell volume 84 μm^3, WBC count 7,290/mm^3, neutrophils 56.5%, sodium 139 mmol/L, potassium 4.3 mmol/L, total protein 76 g/L, blood glucose 2.93 g/L, urea 0.24 g/L, creatinine 7 mg/L, HbA1c 10.2%, thyroid stimulating hormone 1.504 mU/L (normal ranges not provided) and, urine analysis revealed proteinuria 0.31 g/L (0.40 g/24 hours) and microalbuminuria 203.4 mg/L (264.4 mg/24 hours). He was treated with insulin, metformin, gliclazide, liraglutide and received dietary advice. It was reported that anti-GAD, anti-thyroglobulin and anti-thyroperoxidase antibodies and peptide C tests were in progress (results not provided). On [redacted] (study day 36), the event of Type 2 diabetes mellitus was considered resolved (blood glucose values not reported) and the subject was discharged.

The investigator assessed the event of Type 2 diabetes mellitus as serious and not related to the study drug but related to concurrent condition.

There was no change in the study drug due to the event of Type 2 diabetes mellitus. He received a total of six doses of the study drug with the last dose administered on [redacted] (study day 141).

The subject completed the study follow-up visit on [redacted] (study day 281).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Worsening chronic idiopathic urticaria
MedDRA Preferred Term: Idiopathic urticaria

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 1 year and 3 months prior to her study start. The subject's concomitant CIU medication was fexofenadine.

Her concurrent condition included hypertension. Concomitantly, she was receiving enalapril maleate, for conditions other than CIU.

On [redacted], her baseline hematological tests were normal.

The subject received a total of six doses of the study drug with the latest dose administered on [redacted] study day 141). This was also the last dose of study drug prior to the event of idiopathic urticaria.

On [redacted] (study day 274), 133 days after the receipt of the last dose of study drug, the subject was diagnosed with mild worsening of chronic idiopathic urticaria (idiopathic urticaria), assessed as serious; unrelated to the study drug, resulting in hospitalization. She presented with isolated, small wheals and erythematous spots. During hospitalization, C-reactive protein and erythrocyte sedimentation rate were found to be elevated (12.9 mg/L and 18 mm/h, respectively; normal range not provided), C3 and C4 complements were found to be decreased. There was also a positive result for ANA1 and ANA2 titer. Autologous serum skin test, lupus anticoagulant test, stool examination (for ova and parasites) and *Helicobacter pylori* antibodies were also negative. She was observed for suspected vascular disease. On [redacted] (study day 275), laboratory tests showed the platelet count at 402 × 10^3/µL (normal range: 140-400 × 10^3/µL), WBC count 5.82 × 10^3/µL (normal range: 3.8-10.7 × 10^3/µL), blood hemoglobin12.4 g/dL (normal range: 11.6-16.4 g/dL), RBC count 4.23 × 10^3/µL and lymphocytes 40.9% (normal range not

provided). On [redacted] (study day 276), skin photo tests with UV A and UV B were negative. She was treated with intramuscular clemastine, levothyroxine sodium, topical hydrocortisone and clobederm. On [redacted] (study day 277), capillaroscopy showed an individual focus of several ramified hemorrhages, image consistent with anti-phospholipid syndrome. Isolated neo-angiogenetic loops were seen but with no evidence of specific microangiopathy. On [redacted] (study day 278), endoscopy of the upper gastrointestinal tract showed a distinctive, asymmetrically deformed esophageal ampulla and mildly thickened mucosal folds. It was reported that the mycological test for mycosis was negative. On [redacted] (study day 281), a skin biopsy was performed and immunofluorescence showed no evidence of anti-basement membrane, anti-stratum spinosum or anti-C3c complement antibodies. On the same day (study day 281), the event of idiopathic urticaria was considered resolved and the subject was discharged from hospital in good general condition.

The investigator assessed the event of idiopathic urticaria as serious and not related to the study drug but related to the disease under study.

There was no change in the study drug due to the event of idiopathic urticaria as the subject completed her study treatment prior to the occurrence of the event.

The subject completed the study follow-up visit on [redacted] (study day 281).

1.2.2 Narratives for subjects in the Xolair arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (75 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Exacerbation of gastroesophageal reflux disease
MedDRA Preferred Term: Gastroesophageal reflux disease

Subject [redacted] is a [redacted] year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 75 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 49 years and 10 months prior to her study start. The subject's concomitant CIU medication was cetirizine.

Her past history included [redacted]. Her concurrent conditions included arthritis, poor bladder control, generalized fatigue, worsening abdominal discomfort, worsening chest discomfort mild diaphoresis, dizziness, worsening headache, allergic rhinitis, asthma, hypercholesterolemia, and hypertension. Concomitantly, she was receiving

hydrochlorothiazide, metoprolol, lisinopril, lovastatin, tramadol, tolterodine tartrate, alendronate sodium, vitamin D and omeprazole for conditions other than CIU.

On [redacted] her baseline laboratory tests were normal except low absolute neutrophil count 0.93 × 10^3/µL (normal range: 1.96-7.23 × 10^3/µL), WBC count, 3.40 × 10^3/µL (normal range: 3.8-10.7 × 10^3/µL) and neutrophil segmented percent 27.3% (normal range: 40.5-75%) and high eosinophil count 7% (0-6.8%) and lymphocyte percent 57.7% (normal range: 15.4-48.5%).

The subject received a total of six doses of the study drug with the latest dose administered on [redacted] (study day 142). This was also the last dose of study drug prior to the event of gastroesophageal reflux disease.

On [redacted] (study day 145), three days after the receipt of the last dose of study drug, the subject presented with chest pain (assessed as serious; unrelated to study drug) and was hospitalized. On the same day, she was diagnosed with gastroesophageal reflux disease, assessed as serious; unrelated to study drug. It was reported that she had nausea and vomiting. She had negative cardiac enzymes and had no specific changes on the electrocardiogram with ST depression of only 1 mm in V2-V5 and T wave inversion in V2-V4. It was reported that chest pain was due to worsening of gastroesophageal reflux disease. On the same day, her chest pain resolved. On [redacted] (study day 146), the event of worsening of gastroesophageal reflux disease was considered resolved and she was discharged from the hospital.

The investigator assessed the event of worsening of gastroesophageal reflux disease as serious and not related to the study drug. No other possible etiological factors were reported.

There was no change in the study drug due to the event of gastroesophageal reflux disease as the subject completed her study treatment prior to the occurrence of the event.

The subject discontinued from the study and did not complete the follow up period as a result of subject/legal guardian decision to withdraw on [redacted] (study day 402).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Acute appendicitis
MedDRA Preferred Term: Appendicitis

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 17 years prior to his study start. The subject's concomitant CIU medications were cetirizine and loratadine.

His medical history included [redacted]. His concurrent conditions included asthma and hypertension. Concomitantly, he was receiving salbutamol/salbutamol sulfate for conditions other than CIU.

On [redacted] his baseline laboratory tests were normal except high absolute eosinophil count 0.39 × 10^3/µL (normal range: 0-0.30 × 10^3/µL), eosinophil percent 8.1% (normal range: 0-2.8%) and monocyte percent 11.9% (normal range: 4-8%)

The last dose of study drug prior to the event of appendicitis was administered on [redacted] (study day 85).

On [redacted] (study day 98), 13 days after the receipt of the last dose of study drug, the subject presented to the emergency room with abdominal pain, nausea, constipation, right quadrant pain and vomiting. The laboratory work-up showed ALT 118 U/L (normal range: 0-55 IU/L) and AST 47 IU/L (normal range: 5-34 IU/L). Urine analysis showed no significant findings. An abdominal and pelvic CT scan showed acute appendicitis and marked hepatic steatosis. The subject was diagnosed with moderate acute appendicitis (appendicitis), which was assessed as serious; unrelated to study drug. On the same day, around 4 pm he underwent a laparoscopic appendectomy and recovered from acute appendicitis. On [redacted] (study day 99), he was discharged from the hospital.

The investigator assessed the event of appendicitis as serious and not related to the study drug. No other possible etiological factors were reported.

There was no change in study drug due to the event of appendicitis. The subject received six doses of the study drug with the latest dose administered on [redacted] (study day 141)

The subject completed the study follow-up visit on [redacted] (study day 278).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (75 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Acute exacerbation of urticaria
MedDRA Preferred Term: Urticaria

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 75 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 2 years and 10 months prior to her study start. The subject's concomitant CIU medication was loratadine.

The patient had a history of [redacted] dating to [redacted]. She had food allergies to [redacted]. Her past history included [redacted] her [redacted]. There was no history of asthma. There had been a long standing epinephrine pen prescription which was re-started in [redacted] BP was 110/80 in [redacted] She was receiving immunotherapy allergy injections from allergist in [redacted] Her concurrent conditions included allergic rhinitis (since [redacted] and angioedema (since [redacted]. Concomitantly, she was receiving ethinyl estradiol/norgestrel, for conditions other than CIU. During the study, the patient took per protocol rescue doses of diphenhydramine on a when needed basis, in this case, for both ongoing hives and angioedema. The rescue dosing pattern increased from zero on [redacted] and then took 1 tablet each on [redacted] followed by 2 tablets on [redacted]. Similarly, the patient's hive number score and itch scores increased from 0 on the mornings of [redacted] and [redacted] to scores of 3 and 2 (scale of 0-3) on the evening of [redacted] In the morning of [redacted] (during the final study drug dosing) the scores were 2 and 2 and they progressed to maximal levels of 3 and 3 in the evening of [redacted] prior to the event on [redacted] described below.

On [redacted] her baseline hematological tests were normal.

The subject received a total of six doses of the study drug with the latest dose administered [redacted] (at 9:50 am, study day 141). Consistent with the hive number diary score rising to 2 and itch score rising to 2 (scale of 0-3) in the morning of [redacted] the patient reported that one of her typical hives and itch flares was occurring as early as 11 am on that day. This was also the last dose of study drug prior to the event of urticaria. At 11:00 PM on that day, the patient noted increased hives as reported later to the PI and took 1 rescue 25 mg diphenhydramine tablet in response to the late evening hives.

On [redacted] (study day 142), one day after the receipt of the last dose of study drug, the subject awakened with abdominal cramps, sweating, diarrhea, acute hives on face and arms as angioedema, itching, swollen face (lip and eye) and difficulty swallowing at 0100 hours in the morning leading to an ER visit with triage vital signs taken at 2:29 am. The patient reported that the symptoms at 0100 hours on [redacted] were more intense than her normal flares of CIU but were similar to highly intense CIU flares that she had experienced prior to the study and recalled one such event with certainty. Her reason for stating the event was worse than a typical flare was that her "whole face" was disfigured due to swelling.

Respiratory exam in the ER was normal for auscultation with no wheezes noted and O_2 saturation was 100% on room air, BP was 110/70, pulse 87 at 2:29 am and the ER physician stated no abdominal pain, no nausea, and no vomiting were presents. Hives was the only skin finding by the ER physician and pharyngeal exam was normal without throat swelling.

The ER physician found no edema at any site. She was found to have pruritic hives of face and arms. An ER nurse stated that pruritus exacerbation during the acute event did not occur until [redacted] (> 15 hours after the last dose of study drug). She was diagnosed with severe acute exacerbation of urticaria (urticaria; assessed serious; unrelated to the study drug) and at 3.30 am she received treatment with IM methylprednisolone sodium succinate and IM epinephrine. No intravenous infusion was deemed necessary. The same day (37 minutes later), the subject was discharged to walk out of the ER at 0407 hours, feeling improved , alert and oriented with no acute distress. On 22 and [redacted] (study day 143), she took oral prednisone 20 mg, prescribed by the ER physician and the event of urticaria was considered resolved on [redacted] By the evening of [redacted] both the hives score and the itch score had returned to 0. She was able to get back to work and was feeling better.

The investigator assessed the event of urticaria as serious and not related to the study drug but related to disease under study. The prevalence of intestinal symptoms in CIU is reported as increased to values higher than in control patients (Schmidl M. Derm Wochen 45: 481, 1964) and endoscopy findings are common with eosinophilic/mononuclear infiltrates, chronic inflammation, intestinal metaplasia, mucosal edema and mucosal atrophy present in 75% of cases investigated (Patriarca G. Allergol Immunopath 6: 379, 1978).

There was no change in the study drug due to the event of urticaria as the subject completed her study treatment prior to the occurrence of the event.

The subject completed the study follow-up visit on [redacted] (study day 290).

Subject No.: [redacted]
Site No.: [redacted]
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Serious: No
Suspected Relationship to Xolair: N/A
Event Date: Unspecified date [redacted]
Verbatim Term: Drug exposure during pregnancy
MedDRA Preferred Term: Maternal exposure during pregnancy
Serious: Yes
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Therapeutic medical abortion
MedDRA Preferred Term: Abortion induced

Subject [redacted] is a [redacted] year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 6 years and 6 months prior to her study start. The subject's concomitant CIU medication was cetirizine.

No medical history was reported. Her concurrent conditions included bradycardia. Concomitantly, she was receiving desogestrel/ethinyl estradiol for conditions other than CIU.

On [redacted], her baseline laboratory tests were normal.

The subject had received six doses of the study drug with the latest dose administered on [redacted] (study day 138). This was the last dose of study drug prior to the events of drug exposure during pregnancy and therapeutic medical abortion.

On an unspecified date of [redacted] the urine-HCG and an ultrasound scan was done and the subject was found to be pregnant. This was reported as drug exposure during pregnancy. It was her first pregnancy. The date of LMP was reported in [redacted] (exact date unspecified). Her date of conception was unknown and estimated date of delivery was in [redacted] On [redacted] (study day 257), the subject underwent therapeutic medical abortion and pregnancy was terminated.

The investigator considered the event of "therapeutic medical abortion" to be not related to the study drug. No other etiological factor was reported.

The subject completed the study follow-up visit on [redacted] (study day 281).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (300 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Anaphylaxis
MedDRA Preferred Term: Anaphylactic reaction

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 300 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 10 years and 2 months prior to her study start. The subject's concomitant CIU medication was fexofenadine.

No medical history was reported and her concurrent medical conditions included hypothyroidism. Concomitantly, she was receiving levothyroxine sodium, calcium acetate, folic acid, cholecalciferol, hydrochlorothiazide and cyanocobalamin for conditions other than CIU.

On [redacted] her baseline laboratory tests were normal.

The last dose of study drug was administered on [redacted] (study day 141). The anaphylactic event occurred on study day 283, 142 days after the receipt of the final dose of study drug.

From [redacted] (study day 240), through [redacted] (study day 247), the subject was administered dipyrone 500 mg tablets for analgesia, without incident**,** and then dipyrone was restarted on [redacted] (study day 283). Thirty minutes following the re-initiated dipyrone 500 mg dose on [redacted] (study day 283), the subject developed a severe anaphylactic reaction, which was assessed as serious; unrelated to study drug. The anaphylactic reaction included ear ringing, an acute rash covering the full body and a nadir recorded blood pressure of 60/40 mmHg noted by ambulance personnel, recovering to 110/60 mmHg in the emergency room. No dyspnea was noted. She was treated with IV saline, clemastine fumarate, ranitidine and prednisolone. On the same day, the event of anaphylactic reaction was considered resolved.

The investigator considered the event of anaphylactic reaction to be serious and not related to the study drug and related to dipyrone, an agent known to cause anaphylaxis (Leone R. Drug Safety 2005).

The subject received six doses of the study drug with the last dose administered on [redacted] (study day 141).

The subject completed the study follow-up visit on [redacted] (study day 288).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (300 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Hypoglycemic shock
MedDRA Preferred Term: Shock hypoglycaemic

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 300 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 9 years and 4 months prior to his study start. The subject's concomitant CIU medication was fexofenadine.

His concurrent condition included hypertension and Type 2 diabetes mellitus since 1986, with repeated difficulty in controlling serum glucose values and unknown allergy. Concomitantly, he was receiving aspirin, metformin, enalapril maleate, insulin aspart, human insulin isophane suspension, and ascorbic acid, for conditions other than CIU.

On [redacted], his baseline hematological laboratory tests were normal.

The subject received a total of six doses of the study drug with the last dose administered on [redacted] (study day 141). This was also the last dose of study drug prior to the event of shock hypoglycaemic.

On [redacted] (study day 201), 60 days after the receipt of the last dose of study drug, the subject experienced severe hypoglycemic shock (shock hypoglycaemic; assessed as serious and unrelated to the study drug) resulting in hospitalization. At 1800 hours, the subject took one of his diabetes mellitus medications after which he went for a walk, felt unwell and took oral glucose. The subsequent event of hypoglycemic shock happened suddenly and the subject fell unconscious on the street at ~2100 hours. He was taken to the hospital via emergency ambulance He had a laceration at the back of head as a blunt single injury. No peripheral edema was reported. He had normal cardiac rhythm and heart rate. His blood pressure was 160/70 mmHg with a regular heart rate of 120/min without oxygen and his nadir blood sugar was 48 mg/dL in the ambulance. On arrival at the emergency room, his blood pressure values in the first 2 hours varied between 143/75 mmHg and 164/79 mmHg. Pulse was between 73/minute to 90/minute and O_2 saturation by pulse oximetry varied between 97% and 100% in that interval. He was oriented to place and person but not to time. On neurological examination, it was found that strengths were sustained equally on both sides in all extremities. The finger-nose test revealed no pathological findings, sensation equal on both sides, with no dysesthesias. Pupil size was unequal with right> left

and showed prompt light reaction. Occipitally, a contusion mark with slight previous bleeding was seen. On the second hospital day, the subject regained full orientation and pupil size had equalized and oculomotor function was normal. There event was characterized as a short unconsciousness with retrograde amnesia. The cervical spine was free of pressure pain over spinal processes and spinal motion was normal in all axes. The subject was monitored as inpatient for 3 days due to the head trauma. On [redacted] (study day 204), the event of shock hypoglycaemic was considered resolved and the subject was discharged on enalapril, metformin, isophane insulin and insulin aspart.

The investigator assessed the event of shock hypoglycaemic as serious and not related to the study drug but related to concurrent illness.

There was no change in the study drug due to the event of shock hypoglycaemic as the subject completed his study treatment prior to the occurrence of the event.

The subject completed the study follow-up visit on [redacted] (study day 281).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date 1: [redacted]
Verbatim Term 1: Quincke's angioedema, urticaria
MedDRA Preferred Term 1: Urticaria
Suspected Relationship to Xolair: No
Event Date 2: [redacted]
Verbatim Term 2: Quincke`s angioedema, urticaria
MedDRA Preferred Term 2: Angioedema

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] 2011 and received his first study treatment on the same day. The subject was diagnosed with CIU, 20 years and 4 months prior to his study start. The subject's concomitant CIU medication was levocetirizine.

The subject's history of [redacted] dated to [redacted]. His concurrent conditions included angioedema, hypercholesterolemia and hypertension. Concomitantly, he was receiving atorvastatin and losartan for conditions other than CIU.

On [redacted] his baseline laboratory tests were normal except WBC count 12.4 x 10^3/µL (normal range: 3.8-10.7 x 10^3/µL) and neutrophil count 8.9 x 10^3/µL (normal range: 1.96-7.23 x 10^3/µL).

The last dose of study drug prior to the events of urticaria and angioedema was administered on [redacted] (study day 29).

On [redacted] (study day 30), one day after receipt of the last dose of study drug, the subject developed sudden uvula angioedema (Quincke's) with exacerbation of chronic idiopathic urticaria. He was hospitalized with diagnosis of severe angioedema and urticaria (assessed as serious and unrelated to the study drug). No respiratory compromise was noted. He was treated with ciclosporin, clemastine and desloratadine. Methylprednisolone was started in the hospital and there was difficulty with tapering the dose regarding adequate suppression of urticaria. On [redacted] (study day 36), the events of angioedema and urticaria were considered to be resolved and the patient was discharged. On the same day, he was started on an outpatient methylprednisolone taper regimen for 6 days. Cyclosporin 25 mg tid was continued until [redacted] and doxepin 10 mg per day was used following discharge on an ongoing basis..

The investigator assessed the events of urticaria and angioedema as serious and not related to the study drug. In investigator's opinion, the other possible etiological factor included disease under study.

The study drug was permanently discontinued as a result of urticaria and angioedema. He received two doses of the study drug with the last dose administered on [redacted] (study day 29).

The subject completed the study follow-up visit on [redacted] (study day 170).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Idiopathic hypertension
MedDRA Preferred Term: Hypertension
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Right leg's pain
MedDRA Preferred Term: Pain in extremity

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 5 years prior to his study start. The subject's concomitant CIU medication was fexofenadine.

His concurrent conditions included arthrosis, angioedema and hypertension for many years. On [redacted] the subject was classified as having unstable hypertension.

Concomitantly, he was receiving hydrochlorothiazide/valsartan and aspirin, for conditions other than CIU.

At screening, the subject had elevated blood glucose at 131 mg/dL (fasting normal range: 69.8-99.9 mg/dL).

On [redacted], his baseline hematological laboratory tests were normal.

The dose of study drug prior to the event was administered on [redacted] (study day 87).

On [redacted] leg pain was reported and treated with tramadol for one day and ongoing allopurinol 300 mg per day was also started on that day for hyperuricemia (uric acid value not reported).

On [redacted] (study day 113), the subject was hospitalized due to severe idiopathic hypertension (hypertension), assessed as serious; unrelated to the study drug with outpatient values of 230/120 mmHg. Serum creatinine was 0.99 mg/dL, BMI 34 kg/m^2, LDL cholesterol 128 mg/dL, triglycerides 351 mg/dL, uric acid 8.7 mg/dl and fasting serum glucose was 128 mg/dL (normal range not provided). The documented fasting hyperglycemia led to the diagnosis of diabetes mellitus on [redacted] (study day 114), however the subject also had hyperglycemia prior to study drug administration. His routine C-reactive protein was 4.17 mg/dL (normal range not reported). Urinalysis was normal including microscopy. Cardiac ultrasound showed left ventricular hypertrophy with normal contractility and ejection fraction of 67%. Chest X-ray revealed cardiomegaly. He received treatment with lacidipine, valsartan, torasemide, bisoprolol, doxazosin, amlodipine, allopurinol and tramadol during this hospitalization and blood pressure was controlled to values varying from 120-130/80-90 mmHg. 27 days after the receipt of last dose of study drug, the severe pain and dysfunction in right leg (pain in extremity; assessed as serious; unrelated to the study drug), prolonged his hospitalization. The surgeon suspected thrombosis and he was treated with enoxaparin. On that day, the subject was categorized with the adverse events of moderate hypertriglyceridaemia and mild diabetes mellitus (both considered non-serious; unrelated, with the laboratory values noted above. He received treatment with metformin, rosuvastatin, amoxicillin/clavulanate potassium, naproxen (250 mg BID for knee pain, ongoing from [redacted] and isophane insulin (suspension). On [redacted] (study day 115), leg pain became more intensive due to inflammation and the subject could not walk. Laboratory tests showed fibrinogen level was 393.6 mg/dL and D-dimer was 385.11 ng/mL (normal range not reported) and WBC count was 9.82 × 10^3/µL (normal range: 3.8-10.70 × 10^3/µL). Antinuclear antibody (ANA) and antineutrophil cytoplasmic antibody (ANCA) tests were negative. Gouty arthritis was suspected on the basis of signs and uric acid elevation to 8.7 mg/dL (normal range not reported) and abdominal ultrasound showed signs of hepatic steatosis. The diagnosis comorbidities included hyperlipidemia, obesity, hepatic steatosis, suspected arthritis to right knee and unspecified allergy. On [redacted] (study day 116), the subject had an orthopedic consultation and a knee X-ray showed degenerative changes in the right patella, “syndesmophytosis and osteophytosis”. On the same day, the laboratory work-up revealed fibrinogen was 617.1 mg/dL and D-dimer was 317.21 ng/mL (normal range not

provided) and treatment with metformin was switched to insulin which resulted in clinical improvement in diabetes. Glucose and blood pressure during hospitalization were reported to be stable. On [redacted] (study day 117), the event of hypertension was considered resolved but the event of pain in extremity remained unresolved at hospital discharge on that day. Later in the day on [redacted] (study day 117), the subject was readmitted to the same hospital. On [redacted] (study day 121), the Doppler ultrasound exam of lower extremities was performed with no clear abnormality; however, the venous flow response to external pressure was considered dampened. The discharge diagnosis on [redacted] (study day 123), was embolism/thrombosis of unspecified vein, despite the essentially normal findings in the Doppler ultrasound exam. On the same day, treatment with insulin was switched to metformin. Hypertriglyceridaemia and diabetes mellitus were reported as ongoing at the last day of study follow-up at the study competition.

The investigator assessed the events of hypertension and pain in extremity as serious and not related to the study drug. In the investigator's opinion, concurrent illness was the suspected possible cause for these events.

There was no change in the study drug due to the events of hypertension and pain in extremity. He received a total of five doses of the study drug with the last dose administered on [redacted] (study day 115).

The subject completed the study follow-up visit on [redacted] (study day 282).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Unstable angina
MedDRA Preferred Term: Angina unstable

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 7 months prior to her study start. The subject's concomitant CIU medication was fexofenadine.

The subject's medical and surgical history included [redacted]. Her concurrent conditions included hypothyroidism post-thyroidectomy ([redacted]),

hyperlipidemia, coronary artery disease, hypertension and status post myocardial infarction. Concomitantly, she was receiving levothyroxine, isosorbide mononitrate, metoprolol succinate, lacidipine, aspirin and simvastatin for conditions other than CIU.

On [redacted] her baseline laboratory tests were normal.

The subject received a total of six doses of the study drug with the latest dose administered on [redacted] (study day 141). This was also the last dose of study drug prior to the event of unstable angina.

On [redacted] (study day 148), seven days after the receipt of the last dose of study drug, the subject developed severe unstable angina (angina unstable) and was admitted to the cardiological ward. A cardiac ultrasound was performed (results not provided) and ultra-troponin was 0.15 ng/mL (normal range: <0.04 ng/mL). The event of unstable angina was assessed as serious; unrelated to study drug. On the following day, the laboratory evaluation showed troponin I 0.09 ng/mL (normal range: <0.04 ng/mL) and third generation TSH 0.695 mIU/L (normal range 0.350-4.95 mIU/L). ECG revealed normal sinus rhythm at rate of 86 bpm, old inferior wall MI, and flat to negative T waves in V3-V6. She was started on treatment with quinapril, amiloride and hydrochloride/hydrochlorothiazide. On [redacted] (study day 152), an echocardiogram was performed (results not provided). Further coronary bypass and angioplasty were contraindicated based on prior angiography results. On the same day, the event of unstable angina was considered resolved and the subject was discharged on that day.

The investigator assessed the event of unstable angina as serious and not related to the study drug and related to concurrent illness.

There was no change in the study drug due to the event of unstable angina as the subject completed her study treatment prior to the occurrence of the event.

The subject discontinued from the study and did not complete the follow up period as a result of unstable angina on [redacted] (study day 169).

1.3 NARRATIVES FOR SUBJECTS WHO EXPERIENCED ADVERSE EVENTS LEADING TO TREATMENT/STUDY DISCONTINUATION

1.3.1 Narrative for subjects in the Placebo arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Worsening of urticaria
MedDRA Preferred Term: Urticaria

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind,

dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 15 years and 10 months prior to her study start and had prior treatment with zafirlukast, ciclosporin, prednisone, fexofenadine hydrochloride, famotidine, hydroxyzine hydrochloride and methylprednisolone for CIU. The subject's concomitant CIU medication was cetirizine.

Her medical history included [redacted]. Her concurrent conditions included herpes, depression, anxiety, panic attacks and angioedema. No concomitant medication was reported for conditions other than CIU.

On [redacted], her baseline laboratory tests were normal.

The last dose of study drug prior to the event of worsening of urticaria was administered on [redacted] (study day 58).

On [redacted] (study day 68), 10 days after the receipt of the last dose of study drug, the subject experienced severe worsening of urticaria (urticaria) which was assessed as non-serious; unrelated to study drug. She was started on treatment with prednisone on [redacted] (study day 71), and with ranitidine on [redacted] (study day 81). The dose of prednisone was increased from 20 mg to 30 mg on [redacted] (study day 85), and then decreased to 29 mg on [redacted] (study day 110). On [redacted] (study day 147), she was started on open label omalizumab 150 mg which was increased to 300 mg on [redacted] (study day 172). The event of worsening of urticaria was considered resolved on [redacted] (study day 199).

The investigator assessed the event of worsening of urticaria as non-serious and not related to the study drug. No other possible etiological factors were reported.

Study drug was permanently discontinued due to worsening of urticaria. She received a total of three doses of the study drug with the last dose administered on [redacted] (study day 58).

The subject completed the study follow-up visit on [redacted] (study day 199).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Allergic reaction to [redacted]
MedDRA Preferred Term: Drug hypersensitivity
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Cough
MedDRA Preferred Term: Cough

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 7 months prior to her study start. The subject's concomitant CIU medication was fexofenadine.

Her concurrent conditions included near sighted, migraines, sinus headaches, tension headaches, urinary tract infection and allergic rhinitis. No other concomitant medications were reported.

On [redacted] her baseline hematological tests were normal.

The last dose of study drug prior to the event of drug hypersensitivity was administered on [redacted] (study day 57).

On [redacted] (study day 82), 25 days after the receipt of the last dose of study drug, the subject developed severe allergic reaction to ibuprofen (drug hypersensitivity), which was assessed as non-serious and unrelated to the study drug. She received treatment with methylprednisolone sodium succinate, prednisone and hydroxyzine. On [redacted] (study day 86), the event of drug hypersensitivity considered resolved.

The investigator assessed the event of drug hypersensitivity as non-serious and not related to the study drug.

The study drug was permanently discontinued as a result of drug hypersensitivity. She received a total of three doses of the study drug with the last dose administered on [redacted] (study day 57).

On [redacted]2012 (study day 162), 105 days after the receipt of the last dose of study drug, the subject developed mild cough, assessed as non-serious; unrelated to study drug and nasal congestion (assessed as non-serious and unrelated to study drug). On [redacted] (study day 165), she was started on treatment with cold and sinus remedies/paracetamol.

On [redacted] (study day 172), the event of cough and nasal congestion were considered resolved.

The investigator assessed the event of cough as non-serious and not related to the study drug.

There was no change in study drug due to the event of cough as it was discontinued prior to the onset of cough.

The subject completed the study follow-up visit on [redacted] (study day 201).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: CIU exacerbation
MedDRA Preferred Term: Idiopathic urticaria

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 7 months prior to his study start. The subject's concomitant CIU medication was levocetirizine.

His medical history included [redacted]. His concurrent conditions included "[redacted] allergy", near sighted, multiple sclerosis, heart burn, "general muscular pain prn related to workouts" and hypertension. Concomitantly, he was receiving interferon beta-1a for multiple sclerosis and amlodipine and ibuprofen, for conditions other than CIU.

On [redacted], his baseline hematological laboratory tests were normal except for low lymphocyte percent 15% (normal range: 15.4-48.5%) and high segmented neutrophils percent 77.5% (normal range: 40.5%-77.5%).

The last dose of study drug prior to the event of idiopathic urticaria was administered on [redacted] (study day 1).

On [redacted] (study day 9), eight days after the receipt of the last dose of study drug, the subject experienced moderate CIU exacerbation (idiopathic urticaria) assessed as non-serious and unrelated to the study drug. He received treatment with prednisone, fluocinonide, ranitidine and fexofenadine. On [redacted] (study day 17), the event of idiopathic urticaria was considered resolved.

The investigator assessed the event of idiopathic urticaria as non-serious and not related to the study drug.

The study drug was permanently discontinued as a result of exacerbated idiopathic urticaria. He received a single dose of the study drug with the last dose administered on [redacted] (study day 1).

The subject completed the study follow-up visit on [redacted] (study day 140).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Rash
MedDRA Preferred Term: Rash
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Asthma exacerbation
MedDRA Preferred Term: Asthma

Subject [redacted] is a [redacted] year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 11 years and 9 months prior to her study start and had prior treatment with loratadine, ranitidine and montelukast sodium for CIU. The subject's concomitant CIU medication was cetirizine.

Her medical history included [redacted]. Her concurrent conditions included hypothyroidism, Graves' disease, obesity, chronic fatigue, [redacted] allergy, [redacted] allergy, [redacted] allergy, hidradenitis suppurativa, allergic rhinitis and asthma. Concomitantly, she was receiving epinephrine and salbutamol/salbutamol sulfate conditions other than CIU.

On [redacted] her baseline laboratory tests were normal except absolute monocyte count $0.37 \times 10^3/\mu L$ (normal range: $0.40\text{-}0.90 \times 10^3/\mu L$).

The last dose of study drug prior to the event of rash was administered on [redacted] (study day 1).

On [redacted] (study day 11), 10 days after the receipt of the last dose of study drug, the subject developed mild rash, assessed as non-serious; unrelated to study drug. On the same day, she also was diagnosed with bronchitis (diagnostic data not provided) and was treated with ascorbic acid, ciprofloxacin and fluticasone propionate/salmeterol xinafoate. On [redacted] (study day 21), the event of rash was considered resolved. On [redacted] (study day 33), the event of bronchitis was considered resolved.

There was no change in study drug due to the event of rash.

The investigator assessed the event of rash as non-serious and not related to the study drug. No other possible etiological factors were reported.

The subject was diagnosed with pharyngitis streptococcal (diagnostic data not provided) on [redacted] (study day 70), which resolved on [redacted](study day 74).

The last dose of study drug prior to the event of asthma was administered on [redacted] (study day 119).

On [redacted] (study day 139), 20 days after the receipt of the last dose of study drug, the subject experienced a toxic chemical (unstated chemical species) exposure which resulted in a mild exacerbation of preexisting asthma, assessed as non-serious; unrelated to study drug. On the same day, she was treated with prednisolone, levosalbutamol hydrochloride/levosalbutamol tartrate and budesonide. On [redacted] (study day 141), the event of exacerbation of preexisting asthma was considered resolved.

The subject was diagnosed with a second episode of pharyngitis streptococcal (diagnostic data not provided) on [redacted] (study day 143), which resolved on [redacted] (study day 169).

The investigator assessed the event of asthma exacerbation as non-serious and not related to the study drug. No other possible etiological factors were reported.

Study drug was permanently discontinued due to asthma exacerbation. She received a total of five doses of the study drug with the last dose administered on [redacted] (study day 119).

The subject completed the study follow-up visit on [redacted] (study day 253).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: Yes
Event Date: [redacted]
Verbatim Term: Bilateral lower extremity edema
MedDRA Preferred Term: Oedema peripheral

Subject [redacted] is a [redacted] year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 14 years prior to her study start. The subject's concomitant CIU medication was loratadine.

Her medical history included [redacted]. Her concurrent conditions included angioedema, laryngeal symptoms, vitiligo, hypothyroidism, multi nodular goiter, iron deficiency, B12 deficiency, back pain, photo sensitivity, pityriasis rosea, uterine fibroids, pollen allergies, Graves' disease, mild leukocytosis, human papillomavirus (HPV), mild depression, [redacted] allergy, allergy to [redacted],

and allergic rhinitis. Concomitantly, she was receiving ethinyl estradiol/levonorgestrel, levothyroxine and vitamin B, for conditions other than CIU.

The last dose of study drug prior to the event of peripheral oedema was administered on [redacted] (study day 114).

On [redacted] (study day 121), 7 days after the receipt of the last dose of study drug, the subject developed moderate bilateral lower extremity edema (peripheral oedema; assesses as non-serious and related to study drug). No treatment was provided for this event; however, the subject received treatment with prednisone for CIU. The outcome of the event was not provided. On [redacted] (study day 129), the subject experienced moderate idiopathic urticaria (chronic idiopathic urticaria exacerbation; non-serious; unrelated), which resolved the same day.

The investigator assessed the event of peripheral oedema as non-serious and related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of peripheral oedema. She received a total of five doses of the study drug with the last dose administered on [redacted] (study day 114).

The subject discontinued from the study and did not complete the follow up period as a result of peripheral oedema on [redacted] (study day 170).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Disease progression-worsening of chronic idiopathic urticaria
MedDRA Preferred Term: Idiopathic urticaria

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 8 months prior to her study start. The subject's concomitant CIU medication was fexofenadine.

Her concurrent condition included angioedema. No other concomitant medications were reported.

On [redacted] her baseline hematological tests were normal except for high absolute neutrophils count of 10.78 × 10^3/µL (normal range: 1.96-7.23 × 10^3/µL), high WBC count of

12.34 × 10^3/µL (normal range: 3.80-10.70 × 10^3/µL) and low lymphocytes percent of 7.6% (normal range: 15-48%).

The last dose of study drug prior to the event of idiopathic urticaria was administered on [redacted] (study day 1).

On [redacted] (study day 6), five days after the receipt of the last dose of study drug, the subject experienced severe worsening of chronic idiopathic urticaria (idiopathic urticaria; assessed as non-serious; unrelated to the study drug). No treatment was reported for this event. The outcome of the event of idiopathic urticaria was not provided.

The investigator assessed the event of idiopathic urticaria as non-serious and not related to the study drug.

The study drug was permanently discontinued as a result of idiopathic urticaria. She received a single dose of the study drug with the last dose administered on [redacted] (study day 1).

The subject discontinued from the study and did not complete the follow up period as a result of idiopathic urticaria on [redacted] (study day 20).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Exacerbation of COPD
MedDRA Preferred Term: Chronic obstructive pulmonary disease

A narrative for this subject is provided in Section 1.2.1 Narratives for subjects who experienced a serious adverse event in the Placebo arm.

1.3.2 Narratives for subjects in the Xolair arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (75 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Worsening of CIU
MedDRA Preferred Term: Idiopathic urticaria

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 75 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 8 months prior to his study start and had prior treatment with triamcinolone acetonide, montelukast sodium and hydroxychloroquine sulfate for CIU. The subject's concomitant CIU medication was cetirizine.

No medical history was reported. His concurrent conditions included hypercholesterolemia, allergic rhinitis (since [redacted]), hypertension (since [redacted], and angioedema (since [redacted]). Concomitantly, he was receiving rosuvastatin, potassium chloride and atenolol/chlorthalidone for conditions other than CIU.

On [redacted] his baseline laboratory tests were normal.

The last dose of study drug prior to the event of worsening of chronic idiopathic urticaria was administered on [redacted] (study day 1).

On [redacted] (study day 4), three days after the receipt of the last dose of study drug, the subject experienced severe worsening of pre-existing chronic idiopathic urticaria (idiopathic urticaria) which was assessed as non-serious; unrelated to study drug. He was started on treatment with prednisone. On [redacted] (study day 47), the dose of prednisone was increased from 10 mg to 25 mg till [redacted] (study day 48). The event of worsening of chronic idiopathic urticaria was considered resolved on [redacted] (study day 48).

The investigator assessed the event of worsening of chronic idiopathic urticaria as non-serious and not related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of worsening of chronic idiopathic urticaria. He received a total of two doses of the study drug with the last dose administered on [redacted] (study day 30).

The subject completed the study follow-up visit on [redacted] (study day 163).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Abdominal pain
MedDRA Preferred Term: Abdominal pain
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Fluid accumulation in right knee (2nd episode)
MedDRA Preferred Term: Joint effusion

Subject [redacted] is a [redacted] year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized,

double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 1 year and 8 months prior to her study start. The subject's concomitant CIU medication was cetirizine.

Her medical history included [redacted]. Her concurrent conditions included gastroesophageal reflux disease, heartburn, hypothyroidism and inflammatory arthritis (all since [redacted] and angioedema (since [redacted] . Concomitantly, she was receiving levothyroxine sodium and ranitidine hydrochloride for conditions other than CIU.

On [redacted] her baseline laboratory tests were normal except high platelet count 517 × 10^3/µL (normal range: 140-400 × 10^3/µL).

The dose of study drug prior to the event of abdominal pain was administered on [redacted] (study day 57).

On [redacted] (study day 60), three days after the receipt of the last dose of study drug, the subject experienced mild abdominal pain (assessed as non-serious; unrelated to study drug). On [redacted] (study day 61), the event of abdominal pain was considered resolved.

There was no change in the study drug due to the event of abdominal pain.

The investigator assessed the event of abdominal pain as non-serious and not related to the study drug. No other possible etiological factors were reported.

On [redacted] (study day 76), the subject developed 1st episode of moderate joint effusion (fluid accumulation; non-serious; unrelated to study drug). On the same day, she was started on prednisone and the event of 1st episode of joint effusion was considered resolved.

The last dose of study drug was administered on [redacted] (study day 85).

On [redacted] (study day 85), on the day of the last dose of study drug, the subject developed a 2nd episode of moderate joint effusion with arthrocentesis performed, which was assessed as non-serious; unrelated to study drug. On the same day (study day 85), she was started on treatment for inflammatory arthritis with intra-articular triamcinolone acetonide (using a local lidocaine hydrochloride injection as anesthetic) and ongoing sulfasalazine 500 mg BID. On that day, the event of joint effusion (fluid accumulation) was considered resolved.

The investigator assessed the event of 2nd episode of joint effusion as non-serious and not related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of 2nd episode of joint effusion. She received a total of four doses of the study drug with the last dose administered on [redacted] study day 85).

The subject completed the study follow-up visit on [redacted] (study day 228).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: Yes
Event Date 1: [redacted]
Verbatim Term 1: Worsening swelling of upper lip
MedDRA Preferred Term 1: Lip swelling
Suspected Relationship to Xolair: Yes
Event Date 2: [redacted]
Verbatim Term 2: Worsening swelling upper cheek
MedDRA Preferred Term 2: Swelling
Suspected Relationship to Xolair: Yes
Event Date 3: [redacted]
Verbatim Term 3: Right upper abdominal pain
MedDRA Preferred Term 3: Abdominal pain upper
Suspected Relationship to Xolair: No
Event Date 4: [redacted]
Verbatim Term 4: Swelling upper lip
MedDRA Preferred Term 4: Lip swelling
Suspected Relationship to Xolair: No
Event Date 5: [redacted]
Verbatim Term 5: Hives exacerbation
MedDRA Preferred Term 5: Urticaria
Suspected Relationship to Xolair: Yes
Event Date 6: [redacted]
Verbatim Term 6: Right lower abdominal pain
MedDRA Preferred Term 6: Abdominal pain lower
Suspected Relationship to Xolair: No
Event Date 7: [redacted]
Verbatim Term 7: Bilateral ankle swelling
MedDRA Preferred Term 7: Joint swelling
Suspected Relationship to Xolair: No
Event Date 8: [redacted]
Verbatim Term 8: Bilateral hand/wrist aching
MedDRA Preferred Term 8: Pain in extremity
Suspected Relationship to Xolair: No
Event Date 9: [redacted]
Verbatim Term 9: Bilateral hand/wrist aching
MedDRA Preferred Term 9: Arthralgia

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-

blind, dose-ranging, placebo-controlled study to evaluate efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted], 2 years and 2 months prior to her study start. The subject's concomitant CIU medication was loratadine.

Her medical history included [redacted]. Prior to enrolment in the study the subject had [redacted]. She also found relief of [redacted]. Her concurrent conditions included indigestion, stress headaches, sinusitis, [redacted] allergy, vitamin D insufficiency, intermittent joint pain, mild anemia, benign nevi, intermittent common cold, menstrual cramps and allergic rhinitis. Concomitantly, she was receiving ethinyl estradiol/ferrous fumarate/norethisterone acetate, ibuprofen, aspirin/caffeine/paracetamol, multivitamins, guaifenesin, cold and sinus remedies, calcium carbonate and for conditions other than CIU.

On [redacted] (study day 1), her baseline laboratory tests were normal.

The last dose of study drug prior to the events of swelling, and lip swelling was administered on [redacted] (study day 1).

On [redacted] (study day 4), three days after the receipt of the last dose of study drug, the subject developed mild worsening swelling of upper cheek (swelling) and worsening swelling of upper lip (lip swelling), both events were assessed as non-serious; related to study drug. She also experienced oropharyngeal pain, arthralgia and musculoskeletal pain (all non-serious; unrelated to study drug). She did not receive any treatment for worsening swelling of upper cheek and upper lip. The dose of concomitant ibuprofen was increased from 400 mg to 600 mg. On the same day, the events of worsening of swelling in upper cheek, worsening of swelling in upper lip, oropharyngeal pain, arthralgia and musculoskeletal pain were considered resolved.

There was no change in study drug due to events of swelling and lip swelling.

The investigator assessed the events of swelling and lip swelling as non-serious and related to the study drug. The other possible etiological factor for worsening of swelling in upper lip was reported as disease under study and no other possible etiological factor for worsening of swelling in upper cheek were reported.

The subject experienced severe muscular weakness, pain in extremity and arthralgia (all non-serious; unrelated from [redacted] (study day 27) to [redacted] (study day 29).

The last dose of study drug prior to the events of abdominal pain upper, lip swelling (second episode), abdominal pain lower, urticaria, joint swelling, pain in extremity and arthralgia was administered on [redacted] (study day 30).

On [redacted] (study day 31), one day after the receipt of the last dose of study drug, the subject developed mild right upper abdominal pain (abdominal pain upper), which was assessed as non-serious; related to study drug. On [redacted] (study day 32), two days after the receipt of study drug, she developed a second episode of mild swelling upper lip (lip swelling) and severe hives exacerbation (urticaria), both events were assessed as non-serious; unrelated to study drug. On the same day, she also developed mild oropharyngeal pain (non-serious; unrelated to study drug). No event of dyspnea was reported. On [redacted] (study day 33), three days after the receipt of the last dose of study drug, she developed moderate peripheral edema (non-serious; unrelated to study drug). On the same day, the events of peripheral edema, oropharyngeal pain and swelling upper lip were considered resolved. On [redacted] (study day 34), four days after the receipt of the last dose of study drug, she developed severe right lower abdominal pain (abdominal pain lower), which was assessed as non-serious; related to study drug. She did not receive any treatment for right upper and lower abdominal pain. On [redacted] (study day 35), the events of abdominal pain upper and abdominal pain lower were considered resolved. On [redacted] (study day 36), she received treatment with prednisone for chronic idiopathic urticaria and developed mild joint swelling, pain in extremity and arthralgia. All the three events were assessed as non-serious; unrelated to study drug. On the same day (study day 36), the events of joint swelling, pain in extremity and arthralgia were considered resolved. On [redacted] (study day 37), the event of urticaria was considered resolved.

There was no change in study drug due to events of lip swelling, abdominal pain upper and abdominal pain lower The subject permanently discontinued study treatment due to the events of urticaria, joint swelling, pain in extremity and arthralgia and received a total of two doses of study treatment prior to discontinuation with the latest dose administered on [redacted] (study day 30).

The investigator assessed the events of abdominal pain upper and abdominal pain lower as non-serious and related to study drug. No other possible etiological factors were reported.

The investigator assessed the events of urticaria, lip swelling, joint swelling, pain in extremity and arthralgia as non-serious and not related to the study drug. No other possible etiological factors were reported.

The subject completed the study follow-up visit on [redacted] (study day 170).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Headache
MedDRA Preferred Term: Headache
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Joint pain
MedDRA Preferred Term: Arthralgia

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 33 years and 1 month prior to her study start. The subject's concomitant CIU medication was fexofenadine.

No medical history was reported. Her concurrent conditions included anxiety and back pain. Concomitantly, she was receiving tramadol and alprazolam for conditions other than CIU

On [redacted] her baseline laboratory tests were normal.

The last dose of study drug prior to the events of joint pain and headache was administered on [redacted] (study day 1).

On [redacted] (study day 26), 25 days after the receipt of the last dose of study drug, the subject developed moderate joint pain (arthralgia) and headache. Both the events were assessed as non-serious; unrelated to study drug. She did not receive any treatment for both the events. On [redacted] (study day 28), she received second dose of study drug. On [redacted] (study day 42), the event of headache resolved and the outcome of arthralgia was not provided.

The investigator assessed the events of arthralgia and headache as non-serious and not related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of arthralgia and headache. She received a total of two doses of the study drug with the last dose administered on [redacted] (study day 28).

The subject discontinued from the study and did not complete the follow up period as a result of arthralgia and headache on [redacted] (study day 83).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (75 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Hives exacerbation
MedDRA Preferred Term: Urticaria

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 75 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 3 years and 4 months prior to his study start. The subject's concomitant CIU medication was fexofenadine.

The subject had medical history of [redacted] His concurrent conditions included diarrhea and abdominal cramping, gastroesophageal reflux, atelectasis persistent linear density at cardiac apex on chest X-ray and angioedema. Concomitantly, he was receiving pantoprazole and famotidine for conditions other than CIU.

On [redacted] his baseline laboratory tests were normal.

On [redacted] (study day 15), the subject developed mild influenza like illness (non-serious; unrelated) and severe idiopathic urticaria (CIU exacerbation non-serious; unrelated). On the same day, he was started on treatment with loratadine and cetirizine for urticaria. On [redacted] (study day 23), the event of influenza like illness resolved and on [redacted] (study day 29), the event of idiopathic urticaria was considered resolved.

The last dose of study drug prior to the event of urticaria was administered on [redacted] (study day 29).

On [redacted] (study day 54), 25 days after the receipt of the last dose of study drug, the subject again developed severe influenza like illness (non-serious; unrelated) and severe urticaria (hives exacerbation), assessed as non-serious; unrelated to study drug. On the following day, the event of influenza like illness resolved. He received treatment with prednisone, triamcinolone acetonide, hydroxyzine hydrochloride and epinephrine for urticaria. On [redacted] (study day 69), the subject developed a third episode of moderate influenza like illness (non-serious; unrelated). No treatment was reported for influenza like illness. On [redacted] (study day 71), he developed moderate nausea and mild chest discomfort (both non-serious; unrelated). On [redacted] (study day 72), the events of urticaria, third episode influenza like illness, nausea and chest discomfort were considered resolved.

The investigator assessed the event of urticaria (hives exacerbation) as non-serious and not related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of urticaria. He received a total of two doses of the study drug with the last dose administered on [redacted] (study day 29).

The subject completed the study follow-up visit on [redacted] (study day 142).

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date 1: [redacted]
Verbatim Term 1: Quincke's angioedema, urticaria
MedDRA Preferred Term 1: Urticaria
Suspected Relationship to Xolair: No
Event Date 2: [redacted]
Verbatim Term 2: Quincke's angioedema, urticaria
MedDRA Preferred Term 2: Angioedema

A narrative for this subject is provided in Section 1.2.2 Narratives for subjects who experienced serious adverse event in Xolair arm.

Subject No.: [redacted]
Site No.: [redacted]
Serious: Yes
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Unstable angina
MedDRA Preferred Term: Angina unstable

A narrative for this subject is provided in Section 1.2.2 Narratives for subjects who experienced serious adverse event in Xolair arm.

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (300 mg every 4 weeks)
Suspected Relationship to Xolair: Yes
Event Date: [redacted]
Verbatim Term: Severe headache
MedDRA Preferred Term: Headache

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 300 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 8 months prior to her study start and had prior treatment with cetirizine and desloratadine for CIU. The subject's concomitant CIU medication was fexofenadine.

No medical history and concurrent conditions were reported. Concomitantly, she was receiving ethinyl estradiol/gestodene for conditions other than CIU.

On [redacted], her baseline laboratory tests were normal.

The last dose of study drug prior to the event of headache was administered on [redacted] (study day 30).

On [redacted] (study day 30), on the day of the second dose of study drug, the subject developed severe headache, which was assessed as non-serious; related to study drug. On [redacted] (study day 61), she received the third dose of study drug. On [redacted] (study day 62), she was started on treatment with ibuprofen, metoclopramide hydrochloride and codeine phosphate. On [redacted] (study day 136), the event of headache was considered resolved.

The investigator assessed the event of headache as non-serious and related to the study drug. No other possible etiological factors were reported.

The study drug was permanently discontinued as a result of headache. She received a total of three doses of the study drug with the last dose administered on [redacted] (study day 61).

The subject discontinued from the study and did not complete the follow up period as a result of disease progression on [redacted] (study day 146).

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (300 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Pruriginous erythematous hives
MedDRA Preferred Term: Urticaria

Subject [redacted] is a [redacted]-year old [redacted] male with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 300 mg group on [redacted] and received his first study treatment on the same day. The subject was diagnosed with CIU, 18 years and 2 months prior to his study start and had prior treatment with hydroxyzine,

cetirizine and dexchlorpheniramine maleate for CIU. The subject's concomitant CIU medication was desloratadine.

No medical history was reported. His concurrent conditions included dyslipidemia, "hernia hiatale", eczema, angioedema and hypercholesterolemia. Concomitantly, he was receiving rosuvastatin and esomeprazole magnesium for conditions other than CIU.

On [redacted] his baseline laboratory tests were abnormal with WBC count 11.14 × 10^3/µL (normal range: 3.80-10.70 × 10^3/µL), RBC count 3.9 × 10^6/µL (normal range: 4.5-6.4 × 10^6/µL), absolute neutrophil count 8.90 × 10^3/µL (normal range: 1.96-7.23 × 10^3/µL), lymphocyte percent 12.6% (normal range: 15-48.5%), hemoglobin 12.1 g/dL (normal range: 12.7-18.1 g/dL) and hematocrit 35% (normal range: 39-54%).

The last dose of study drug prior to the event of urticaria was administered on [redacted] (study day 1).

On [redacted] (study day 11), 10 days after the receipt of the first and final dose of study drug, the subject experienced severe pruriginous erythematous hives (urticaria) which was assessed as non-serious; unrelated to study drug. On the same day treatment with desloratadine was switched to ciclosporin. On [redacted] (study day 12), the event of urticaria was considered resolved. On the same day, he experienced mild decreased appetite. The outcome of decreased appetite was not provided.

The investigator assessed the event of urticaria as non-serious and not related to the study drug. No other possible etiological factors were reported.

Study drug was permanently discontinued due to urticaria. He received a single dose of the study drug, administered on [redacted] (study day 1).

The subject discontinued from the study and did not complete the follow up period as a result of urticaria on [redacted] (study day 27).

1.4 NARRATIVES FOR SUBJECTS WHO BECAME PREGNANT DURING THE STUDY

1.4.1 Narratives for subjects in the Placebo arm

Subject No. [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: N/A
Event Date: [redacted]
Verbatim Term: Pregnancy
MedDRA Preferred Term: Pregnancy

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted], a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of

Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the placebo group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU, 2 years and 6 months prior to her study start. The subject's concomitant CIU medication was loratadine.

The subject had a medical history of [redacted]. Her concurrent conditions included gastroesophageal reflux disease, occasional headaches of unknown etiology, occasional migraines, cyclic menstrual cramps, obesity, allergic rhinitis and angioedema. Concomitantly, she was receiving unspecified minerals/multivitamins, ranitidine, aspirin/caffeine/paracetamol and ibuprofen for conditions other than CIU.

On [redacted], her baseline laboratory tests were normal.

The subject had received six doses of the study drug with the latest dose administered on [redacted] (study day 141). This was the last dose of study drug prior to the event of pregnancy.

The subject's last menstrual period (LMP) date was reported to be on [redacted] (study day 226). On [redacted] (study day 246), the subject conceived and on [redacted] (study day 281), an unspecified pregnancy test was positive (gestational age not provided). Her current weight was 115 kg, Para was 1 and Gravida 3. It was reported that exposure of study drug was at week 1.

The subject completed the study follow-up visit on [redacted] (study day 289).

The subject's estimated date of delivery is [redacted] (study day 526). The outcome of the event of pregnancy was reported as ongoing at the last day of study follow-up.

1.4.2 Narratives for subjects in the Xolair arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Urticaria
MedDRA Preferred Term: Hives exacerbation
Suspected Relationship to Xolair: N/A
Event Date: [redacted]
Verbatim Term: Pregnancy
MedDRA Preferred Term: Pregnancy

Subject [redacted] is a [redacted]-year old [redacted] female with chronic idiopathic urticaria (CIU) enrolled in the Q4881g protocol on [redacted] a phase III, multicenter, randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of

Xolair® (omalizumab) in CIU patients who remain symptomatic despite antihistamine treatment (H1).

The subject was randomized to the omalizumab 150 mg group on [redacted] and received her first study treatment on the same day. The subject was diagnosed with CIU on [redacted] 7 years and 11 months prior to her study start. The subject's concomitant CIU medication was cetirizine.

Her medical history included [redacted]. Her concurrent conditions included obesity, allergic rhinitis and angioedema (since [redacted]). Concomitantly, she was receiving medroxyprogesterone acetate for conditions other than CIU.

On [redacted], her baseline laboratory tests were normal.

The last dose of study drug prior to the event of urticaria was administered on [redacted] (study day 56).

On [redacted] (study day 84), 28 days after the receipt of the last dose of study drug, the subject developed moderate urticaria (hives exacerbation; assessed as non-serious; unrelated). No treatment was reported for the event. On the same day, the event of urticaria was considered resolved.

The investigator assessed the event of urticaria as non-serious and not related to the study drug.

There was no change in the study drug due to the event of urticaria.

The subject had received six doses of the study drug with the latest dose administered on [redacted] (study day 141). This was the last dose of study drug prior to the event of pregnancy.

The subject's last menstrual period (LMP) date was reported to be on [redacted] (study day 269). On [redacted] (study day 281), the subject was found to be pregnant (gestational age not provided). She was on contraception device since [redacted] (study day 27) and it was reported that her conception date was unknown.

The subject completed the study follow-up visit on [redacted] (study day 281).

The subject's estimated date of delivery is [redacted] (study day 549). The outcome of the event of pregnancy was reported as ongoing at the last day of study follow-up.

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: N/A
Event Date: Unspecified date [redacted]
Verbatim Term: Drug exposure during pregnancy
MedDRA Preferred Term: Maternal exposure during pregnancy
Serious: Yes
Suspected Relationship to Xolair: No
Event Date: [redacted]
Verbatim Term: Therapeutic medical abortion
MedDRA Preferred Term: Abortion induced

A narrative for this subject is provided in Section 1.2.2 Narratives for subjects who experienced serious adverse event in Xolair arm

1.5 NARRATIVES FOR SUBJECTS WHO EXPERIENCED ADVERSE EVENTS OF SPECIAL INTEREST

1.5.1 Narratives for subjects in the Placebo arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Allergic reaction to ibuprofen
MedDRA Preferred Term: Drug hypersensitivity

A narrative for this subject is provided in Section 1.3.1 Narratives for subjects who experienced adverse event leading to discontinuation in Placebo arm.

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Placebo (every 4 weeks)
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Rash
MedDRA Preferred Term: Rash
Suspected Relationship to Placebo: No
Event Date: [redacted]
Verbatim Term: Asthma exacerbation
MedDRA Preferred Term: Asthma

A narrative for this subject is provided in Section 1.3.1 Narratives for subjects who experienced adverse events leading to discontinuation in Placebo arm.

1.5.2 Narratives for subjects in the Xolair arm

Subject No.: [redacted]
Site No.: [redacted]
Serious: No
Treatment Arm: Omalizumab (150 mg every 4 weeks)
Suspected Relationship to Xolair: Yes
Event Date 1: [redacted]2
Verbatim Term 1: Worsening swelling of upper lip
MedDRA Preferred Term 1: Lip swelling
Suspected Relationship to Xolair: Yes
Event Date 2: [redacted]
Verbatim Term 2: Worsening swelling upper cheek
MedDRA Preferred Term 2: Swelling
Suspected Relationship to Xolair: Yes
Event Date 3: [redacted]
Verbatim Term 3: Right upper abdominal pain
MedDRA Preferred Term 3: Abdominal pain upper
Suspected Relationship to Xolair: No
Event Date 4: [redacted]
Verbatim Term 4: Swelling upper lip
MedDRA Preferred Term 4: Lip swelling
Suspected Relationship to Xolair: No
Event Date 5: [redacted]
Verbatim Term 5: Hives exacerbation
MedDRA Preferred Term 5: Urticaria
Suspected Relationship to Xolair: Yes
Event Date 6: [redacted]
Verbatim Term 6: Right lower abdominal pain
MedDRA Preferred Term 6: Abdominal pain lower
Suspected Relationship to Xolair: No
Event Date 7: [redacted]
Verbatim Term 7: Bilateral ankle swelling
MedDRA Preferred Term 7: Joint swelling
Suspected Relationship to Xolair: No
Event Date 8: [redacted]
Verbatim Term 8: Bilateral hand/wrist aching
MedDRA Preferred Term 8: Pain in extremity
Suspected Relationship to Xolair: No
Event Date 9: [redacted]
Verbatim Term 9: Bilateral hand/wrist aching
MedDRA Preferred Term 9: Arthralgia

A narrative for this subject is provided in Section 1.3.2. Narratives for subjects who experienced adverse event leading to discontinuation in Xolair arm.

Table 14.1/1
Enrollment by Country and Investigator
Randomized Patients

Region / Country / Investigator Number / Name	Placebo (n=80)	Omalizumab 75mg (n=78)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=319)
US	54 (67.5%)	56 (71.8%)	56 (70.0%)	54 (66.7%)	220 (69.0%)
USA	54 (67.5%)	56 (71.8%)	56 (70.0%)	54 (66.7%)	220 (69.0%)
[redacted]	6 (7.5%)	3 (3.8%)	6 (7.5%)	5 (6.2%)	20 (6.3%)
	2 (2.5%)	3 (3.8%)	6 (7.5%)	3 (3.7%)	14 (4.4%)
	3 (3.8%)	4 (5.1%)	3 (3.8%)	3 (3.7%)	13 (4.1%)
	2 (2.5%)	2 (2.6%)	4 (5.0%)	5 (6.2%)	13 (4.1%)
	6 (7.5%)	3 (3.8%)	2 (2.5%)	2 (2.5%)	13 (4.1%)
	3 (3.8%)	2 (2.6%)	3 (3.8%)	3 (3.7%)	11 (3.4%)
	(0.0%)	6 (7.7%)	2 (2.5%)	3 (3.7%)	11 (3.4%)
	3 (3.8%)	2 (2.6%)	3 (3.8%)	2 (2.5%)	10 (3.1%)
	3 (3.8%)	2 (2.6%)	2 (2.5%)	3 (3.7%)	10 (3.1%)
	5 (6.3%)	1 (1.3%)	3 (3.8%)	(0.0%)	9 (2.8%)
	1 (1.3%)	4 (5.1%)	1 (1.3%)	3 (3.7%)	9 (2.8%)
	1 (1.3%)	3 (3.8%)	1 (1.3%)	3 (3.7%)	8 (2.5%)
	1 (1.3%)	3 (3.8%)	3 (3.8%)	(0.0%)	7 (2.2%)
	1 (1.3%)	3 (3.8%)	(0.0%)	3 (3.7%)	7 (2.2%)
	2 (2.5%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	6 (1.9%)
	(0.0%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	6 (1.9%)
	1 (1.3%)	1 (1.3%)	2 (2.5%)	2 (2.5%)	6 (1.9%)
	4 (5.0%)	(0.0%)	1 (1.3%)	(0.0%)	5 (1.6%)
	2 (2.5%)	(0.0%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
	1 (1.3%)	(0.0%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
	1 (1.3%)	2 (2.6%)	1 (1.3%)	(0.0%)	4 (1.3%)
	(0.0%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
	(0.0%)	2 (2.6%)	(0.0%)	1 (1.2%)	3 (0.9%)
	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_enroll)
Database (CLOSED) Datasets (pat)
: Generated 25JAN13 14:09 Page 1 of 2

Table 14.1/1
Enrollment by Country and Investigator
Randomized Patients

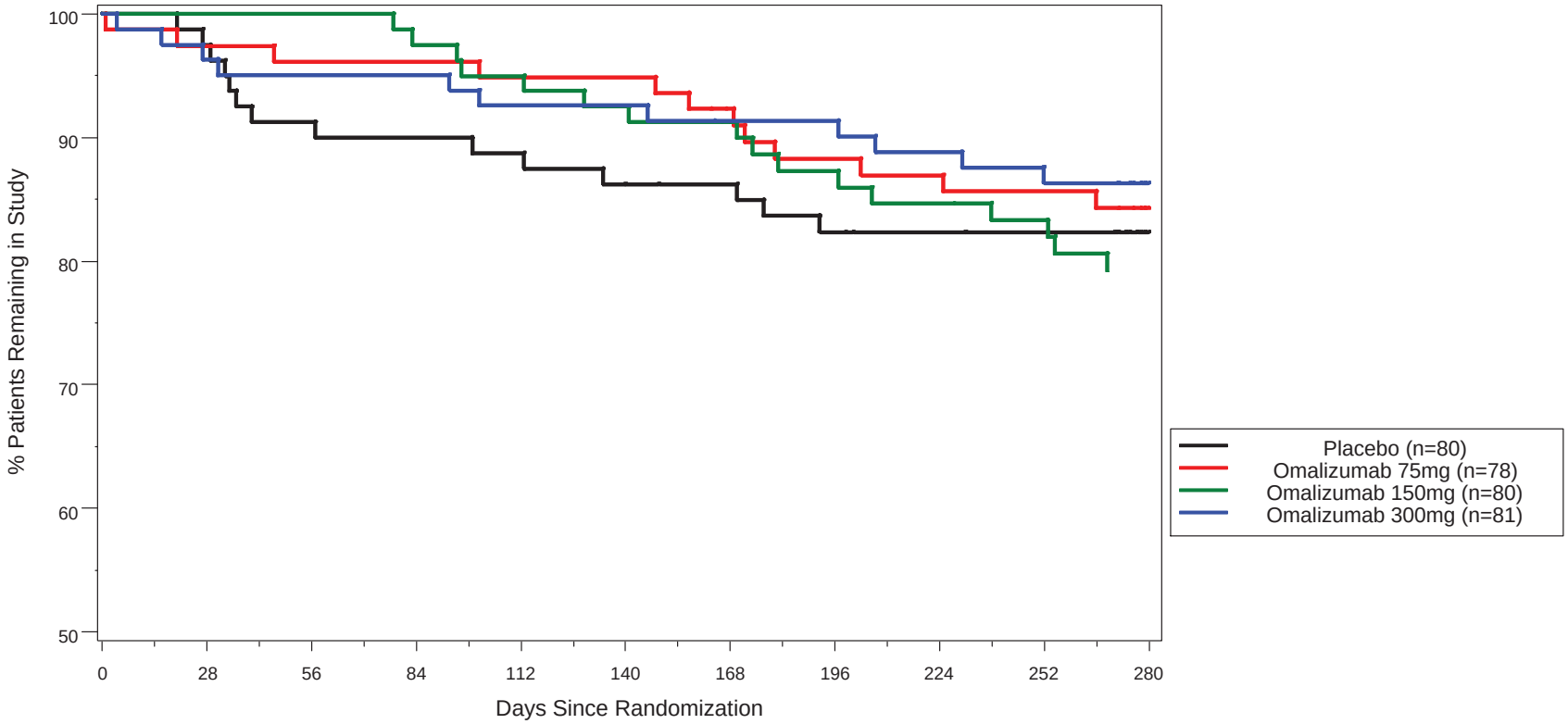
Region / Country / Investigator Number / Name	Placebo (n=80)	Omalizumab 75mg (n=78)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=319)
[redacted]	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
non-US	26 (32.5%)	22 (28.2%)	24 (30.0%)	27 (33.3%)	99 (31.0%)
POL	6 (7.5%)	10 (12.8%)	11 (13.8%)	12 (14.8%)	39 (12.2%)
	4 (5.0%)	7 (9.0%)	9 (11.3%)	8 (9.9%)	28 (8.8%)
	1 (1.3%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	7 (2.2%)
	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GER	10 (12.5%)	3 (3.8%)	6 (7.5%)	7 (8.6%)	26 (8.2%)
	5 (6.3%)	1 (1.3%)	5 (6.3%)	5 (6.2%)	16 (5.0%)
	2 (2.5%)	1 (1.3%)	(0.0%)	1 (1.2%)	4 (1.3%)
	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEN	5 (6.3%)	3 (3.8%)	4 (5.0%)	5 (6.2%)	17 (5.3%)
	2 (2.5%)	1 (1.3%)	3 (3.8%)	3 (3.7%)	9 (2.8%)
	3 (3.8%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	8 (2.5%)
FRA	3 (3.8%)	3 (3.8%)	1 (1.3%)	2 (2.5%)	9 (2.8%)
	2 (2.5%)	1 (1.3%)	(0.0%)	1 (1.2%)	4 (1.3%)
	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ESP	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ITA	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
TUR	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_enroll)
Database (CLOSED) Datasets (pat)
: Generated 25JAN13 14:09 Page 2 of 2

Table 14.1/2
Patient Disposition
Randomized Patients

Status	Placebo (n=80)	Omalizumab 75mg (n=78)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=319)
Received at least one dose of study drug	80 (100.0%)	77 (98.7%)	80 (100.0%)	81 (100.0%)	318 (99.7%)
Completed study drug treatment	61 (76.3%)	67 (85.9%)	64 (80.0%)	73 (90.1%)	265 (83.1%)
Study drug treatment withdrawn					
-Total-	19 (23.8%)	11 (14.1%)	16 (20.0%)	8 (9.9%)	54 (16.9%)
Adverse Event	7 (8.8%)	2 (2.6%)	4 (5.0%)	2 (2.5%)	15 (4.7%)
Lost to follow-up	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
Physician decision to discontinue treatment	(0.0%)	3 (3.8%)	2 (2.5%)	1 (1.2%)	6 (1.9%)
Subject/legal guardian decision to discontinue treatment	1 (1.3%)	3 (3.8%)	5 (6.3%)	3 (3.7%)	12 (3.8%)
Disease Progression	10 (12.5%)	3 (3.8%)	5 (6.3%)	2 (2.5%)	20 (6.3%)
Completed study	65 (81.3%)	64 (82.1%)	64 (80.0%)	69 (85.2%)	262 (82.1%)
Discontinued early from study					
-Total-	15 (18.8%)	14 (17.9%)	16 (20.0%)	12 (14.8%)	57 (17.9%)
Adverse Event	2 (2.5%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
Lost to follow-up	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
Physician decision to withdraw subject from study	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
Subject/legal guardian decision to withdraw	2 (2.5%)	6 (7.7%)	8 (10.0%)	5 (6.2%)	21 (6.6%)
Disease progression	10 (12.5%)	5 (6.4%)	6 (7.5%)	5 (6.2%)	26 (8.2%)

Figure 14.1/1
Patient Retention
Randomized Patients



Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_patret)
Database (CLOSED) Datasets (pat)
: Generated 01MAR13 15:35 Page 1 of 1

Table 14.1/5
Analysis Populations

Region Analysis Population	Placebo	Omalizumab 75mg	Omalizumab 150mg	Omalizumab 300mg	All Patients
Total					
Randomized	80	78	80	81	319
Modified Intention to Treat	80	77	80	81	318
Pharmacokinetic evaluable	80	70	87	81	318
Safety	80	70	87	81	318
US					
Randomized	54	56	56	54	220
Modified Intention to Treat	54	55	56	54	219
Pharmacokinetic evaluable	54	50	61	54	219
Safety	54	50	61	54	219
non-US					
Randomized	26	22	24	27	99
Modified Intention to Treat	26	22	24	27	99
Pharmacokinetic evaluable	26	20	26	27	99
Safety	26	20	26	27	99

Randomized=all randomized patients regardless of whether they received any study drug. Treatment groups defined according to the treatment assigned at randomization by the IxRS. Modified Intention-to-treat=all patients randomized in the study who received at least one dose of study drug. Treatment groups defined according to the treatment assigned at randomization by the IxRS. Pharmacokinetic evaluable=randomized patients who have received at least one dose of study drug and have provided at least one serum sample for determination of omalizumab concentration.
Safety=patients randomized in the study who received at least one dose of study drug. Treatment groups for this population will be defined according to the actual treatment received during the treatment period.

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Database (CLOSED) Datasets (pat)
: Generated 04FEB13 15:59 Page 1 of 1

Table 14.1/3.1
Patient Eligibility
Inclusion and Exclusion Criteria Not Met
Randomized Patients

Inclusion or Exclusion Criterion	Placebo (n=80)	Omalizumab 75mg (n=78)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=319)
Any Reason	2 (2.5%)	7 (9.0%)	5 (6.3%)	7 (8.6%)	21 (6.6%)
Inclusion-2	1 (1.3%)	5 (6.4%)	5 (6.3%)	4 (4.9%)	15 (4.7%)
Exclusion-7	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
Exclusion-10	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
Exclusion-13	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
Exclusion-21	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)

See Table 14.1/3.2 for the description of the individual inclusion and exclusion criteria.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_elig)
Database (CLOSED) Datasets (elig, pat)
: Generated 25JAN13 14:07 Page 1 of 1

Table 14.1/3.2
Patient Eligibility
Description of Inclusion and Exclusion Criteria

Criterion	Description
Inclusion-1	Aged 12 - 75 years (age limits may vary dependent upon regional restrictions)
Inclusion-2	Diagnosis of CIU refractory to H1 antihistamines at the time of randomization, as defined by all of the following: The presence of itch and hives for >= 8 consecutive weeks at any time prior to enrollment despite current use of H1 antihistamine treatment during this time period UAS7 score (range 0 - 42) >= 16 and itch component of UAS7 (range 0 - 21) >= 8 during 7 days prior to randomization (Week 0) In-clinic UAS >=4 on at least one of the screening visit days (Day -14, Day -7 or Day 1) Subjects must have been on an approved dose of an H1 antihistamine for CIU for at least the 3 consecutive days immediately prior to the Day -14 screening visit and must document current use on the day of the initial screening visit CIU diagnosis for >= 6 months
Inclusion-3	Willing to give written informed consent, adhere to the visit schedules and meet study requirements For those subjects below the legal age of consent, the child must be willing to give written informed assent and the parent(s) / guardian(s) must be willing to give written informed consent For subjects below the legal age of consent, both child and parent must be able to adhere to dose and visit schedules and meet study requirements
Inclusion-4	Willing and able to complete a daily symptom eDairy for the duration of the study
Inclusion-5	Subjects must not have any missing eDairy entries in the 7 days prior to randomization
Exclusion-1	Treatment with an investigational agent within 30 days of Day -14
Exclusion-2	Weight less than 20 kg (44 lbs)

Table 14.1/3.2
Patient Eligibility
Description of Inclusion and Exclusion Criteria

Criterion	Description
Exclusion-3	Clearly defined underlying etiology for chronic urticarias other than CIU (main manifestation being physical urticaria). This includes the following urticarias: Acute, solar, cholinergic, heat, cold, aquagenic, delayed pressure or contact As well as the following diseases as these diseases may have symptoms of urticaria or angioedema Urticarial vasculitis, urticaria pigmentosa, erythema multiforme, mastocytosis, hereditary or acquired angioedema, lymphoma, leukemia, or generalized cancer
Exclusion-4	Evidence of parasitic infection defined as having the following three items: Risk factors for parasitic disease (living in an endemic area, chronic GI symptoms, travel within the last 6 months to an endemic area and / or chronic immunosuppression) AND An absolute eosinophil count more than twice the upper limit of normal AND Evidence of parasitic colonization or infection on stool evaluation for ova and parasites. Note that stool ova and parasite evaluation will only be conducted in subjects with both risk factors and an eosinophil count more than twice the upper limit of normal.
Exclusion-5	Atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus or other skin disease associated with itch
Exclusion-6	Previous treatment with omalizumab within a year prior to Day -14
Exclusion-7	Routine (daily or every other day during 5 or more consecutive days) doses of the following medications within 30 days prior to Day -14: systemic or cutaneous (topical) corticosteroids (prescription or over the counter), hydroxychloroquine, methotrexate, cyclosporine, or cyclophosphamide
Exclusion-8	IV immunoglobulin G (IVIG), or plasmapheresis within 30 days prior to Day -14
Exclusion-9	Regular (daily / every other day) doxepin (oral) use within 14 days prior to Day -14
Exclusion-10	Any H2 antihistamine use within 7 days prior to Day -14
Exclusion-11	Any LTRA (montelukast or zafirlukast) within 7 days prior to Day -14

Table 14.1/3.2
Patient Eligibility
Description of Inclusion and Exclusion Criteria

Criterion	Description
Exclusion-12	Any H1 antihistamines at greater than approved doses within 3 days prior to Day -14
Exclusion-13	Subjects with current malignancy, history of malignancy, or currently under work-up for suspected malignancy except non-melanoma skin cancer that has been treated or excised and is considered resolved
Exclusion-14	Hypersensitivity to omalizumab or any component of the formulation
Exclusion-15	History of anaphylactic shock
Exclusion-16	Presence of clinically significant cardiovascular, neurological, psychiatric, metabolic or other pathological conditions that could interfere with the interpretation of the study results and / or compromise the safety of the subjects
Exclusion-17	Medical examination or laboratory findings that suggest the possibility of decompensation of co-existing conditions for the duration of the study. Any items that are cause for uncertainty must be reviewed with the Medical Monitor.
Exclusion-18	Inability to comply with study and follow-up procedures
Exclusion-19	Evidence of current drug or alcohol abuse

Table 14.1/3.2
Patient Eligibility
Description of Inclusion and Exclusion Criteria

Criterion	Description
Exclusion-20	Nursing women or women of childbearing potential, defined as all women physiologically capable of becoming pregnant, including women whose career, lifestyle, or sexual orientation precludes intercourse with a male partner and women whose partners have been sterilized by vasectomy or other means, UNLESS they meet the following definition of post-menopausal: 12 months of natural (spontaneous) amenorrhea or 6 months of spontaneous amenorrhea with serum FSH levels > 40 mIU/mL or 6 weeks post-surgical bilateral oophorectomy (with or without hysterectomy) or hysterectomy OR are using one or more of the following acceptable methods of contraception: surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: IUD, male or female condom with spermicidal gel, diaphragm, sponge, or cervical cap)
Exclusion-21	Contraindications to diphenhydramine: Overreactivity against the agent diphenhydramine, other antihistaminic agents, or other components of this agent; acute bronchial asthma; acute angle-closure glaucoma; pheochromocytoma; hyperplasia of the prostate gland with formation of residual urine; epilepsy; hypokalemia; hypomagnesemia; bradycardia; a congenital long QT syndrome or other clinically significant cardial disorders (especially coronary heart disease, disturbances in conduction, arrhythmias); the simultaneous application of drugs which prolong the QT interval (e.g., antiarrhythmic drugs class IA or III, antibiotics, cisapride, malaria drugs, antihistaminic drugs, neuroleptic drugs) or lead to hypokalemia (e.g., certain diuretic drugs); the simultaneous application of MAO inhibitors; the simultaneous uptake of alcohol

Table 14.1/4
Major Protocol Deviations
Randomized Patients

	Placebo (n=80)	Omalizumab 75mg (n=78)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=319)
-Any deviations-	20 (25.0%)	16 (20.5%)	16 (20.0%)	21 (25.9%)	73 (22.9%)
Concomitant Medication Criteria	18 (22.5%)	11 (14.1%)	11 (13.8%)	15 (18.5%)	55 (17.2%)
Eligibility and Entry Criteria	2 (2.5%)	6 (7.7%)	5 (6.3%)	5 (6.2%)	18 (5.6%)
IP Compliance	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
Informed Consent	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
Study Procedures Criteria	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mpd)
Database (CLOSED) Datasets (devia, pat)
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Table 14.1/7
Baseline Disease Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Positive CU index test					
n	80	77	79	81	317
Yes	25 (31.3%)	18 (23.4%)	16 (20.3%)	21 (25.9%)	80 (25.2%)
No	55 (68.8%)	59 (76.6%)	63 (79.7%)	60 (74.1%)	237 (74.8%)
Presence of thyroperoxidase antibody					
n	79	74	80	81	314
High (>34.99 U/mL)	12 (15.2%)	16 (21.6%)	10 (12.5%)	9 (11.1%)	47 (15.0%)
Normal (<=34.99 U/mL)	67 (84.8%)	58 (78.4%)	70 (87.5%)	72 (88.9%)	267 (85.0%)
Total IgE level (IU/mL)					
n	77	75	74	80	306
Mean (SD)	161.5 (215.1)	195.3 (334.5)	225.2 (612.6)	152.6 (285.2)	182.8 (387.8)
Median	92.0	91.0	71.0	85.5	83.0
Range	1 - 1010	1 - 2030	1 - 5000	1 - 2330	1 - 5000
Duration of CIU (years)					
n	78	76	78	81	313
Mean (SD)	7.0 (9.7)	7.0 (9.7)	7.6 (9.2)	6.2 (8.0)	6.9 (9.1)
Median	3.7	3.8	4.3	3.2	3.7
Range	0.5 - 48.2	0.5 - 50.5	0.5 - 44.4	0.5 - 35.4	0.5 - 50.5
Duration of CIU					
n	78	76	78	81	313
<=1 year	14 (17.9%)	20 (26.3%)	13 (16.7%)	17 (21.0%)	64 (20.4%)
>1 - <2 years	12 (15.4%)	9 (11.8%)	11 (14.1%)	17 (21.0%)	49 (15.7%)
2-10 years	36 (46.2%)	31 (40.8%)	34 (43.6%)	31 (38.3%)	132 (42.2%)
>10 years	16 (20.5%)	16 (21.1%)	20 (25.6%)	16 (19.8%)	68 (21.7%)

^Baseline in-clinic UAS is defined as the largest value among the Day -14 screening visit, Day -7 screening visit and Day 1 Visit.
*Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

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Database (CLOSED) Datasets (pat pateff)
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Table 14.1/7
Baseline Disease Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Previous Number of CIU medications					
n	80	77	80	81	318
Mean (SD)	5.0 (2.8)	4.7 (2.8)	4.5 (3.2)	4.5 (2.3)	4.7 (2.8)
Median	4.5	4.0	4.0	4.0	4.0
Range	1 - 13	1 - 13	1 - 18	1 - 10	1 - 18
Previous Number of CIU medications					
n	80	77	80	81	318
<=2	17 (21.3%)	18 (23.4%)	19 (23.8%)	19 (23.5%)	73 (23.0%)
3-5	33 (41.3%)	34 (44.2%)	40 (50.0%)	33 (40.7%)	140 (44.0%)
>5	30 (37.5%)	25 (32.5%)	21 (26.3%)	29 (35.8%)	105 (33.0%)
Previous Use of Systemic Steroids for CIU					
n	80	77	80	81	318
Yes	31 (38.8%)	41 (53.2%)	32 (40.0%)	36 (44.4%)	140 (44.0%)
No	49 (61.3%)	36 (46.8%)	48 (60.0%)	45 (55.6%)	178 (56.0%)
In-Clinic UAS^					
n	80	77	80	81	318
Mean (SD)	5.3 (0.8)	5.3 (0.8)	5.3 (0.7)	5.3 (0.8)	5.3 (0.8)
Median	5.0	5.0	5.0	5.0	5.0
Range	4 - 6	4 - 6	4 - 6	4 - 6	4 - 6
UAS7*					
n	80	77	80	81	318
Mean (SD)	31.1 (6.7)	31.7 (6.7)	30.3 (7.3)	31.3 (5.8)	31.1 (6.6)
Median	31.5	31.5	30.8	31.5	31.5
Range	16.0 - 42.0	17.0 - 42.0	16.0 - 42.0	19.5 - 42.0	16.0 - 42.0

^Baseline in-clinic UAS is defined as the largest value among the Day -14 screening visit, Day -7 screening visit and Day 1 Visit.
*Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

Table 14.1/7
Baseline Disease Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Weekly itch severity score*					
n	80	77	80	81	318
Mean (SD)	14.4 (3.5)	14.5 (3.6)	14.1 (3.8)	14.2 (3.3)	14.3 (3.5)
Median	14.0	14.0	14.0	14.0	14.0
Range	8.0 - 21.0	8.5 - 21.0	8.0 - 21.0	8.0 - 21.0	8.0 - 21.0
Weekly itch severity score*					
n	80	77	80	81	318
<13	26 (32.5%)	28 (36.4%)	26 (32.5%)	28 (34.6%)	108 (34.0%)
>=13	54 (67.5%)	49 (63.6%)	54 (67.5%)	53 (65.4%)	210 (66.0%)
Weekly number of hives score*					
n	80	77	80	81	318
Mean (SD)	16.7 (4.4)	17.2 (4.2)	16.2 (4.6)	17.1 (3.8)	16.8 (4.3)
Median	18.3	19.0	17.0	18.5	18.5
Range	5.0 - 21.0	7.5 - 21.0	4.5 - 21.0	8.5 - 21.0	4.5 - 21.0
Weekly size of the largest hive score*					
n	80	77	80	81	318
Mean (SD)	15.6 (4.2)	15.5 (4.4)	15.3 (4.2)	15.3 (4.0)	15.4 (4.2)
Median	16.0	15.5	15.0	16.0	15.5
Range	6.0 - 21.0	4.0 - 21.0	6.0 - 21.0	7.0 - 21.0	4.0 - 21.0
Weekly interference with sleep score*					
n	80	77	80	81	318
Mean (SD)	12.6 (4.8)	12.2 (5.3)	12.1 (5.2)	12.2 (4.5)	12.3 (4.9)
Median	13.0	14.0	12.5	12.0	13.0
Range	0.0 - 21.0	0.0 - 21.0	0.0 - 21.0	0.0 - 21.0	0.0 - 21.0

^Baseline in-clinic UAS is defined as the largest value among the Day -14 screening visit, Day -7 screening visit and Day 1 Visit.
*Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_bdc)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 13:57 Page 3 of 5

Table 14.1/7
Baseline Disease Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Weekly interference with daily activities score*					
n	80	77	80	81	318
Mean (SD)	13.0 (4.8)	13.1 (4.6)	12.9 (4.7)	13.0 (3.9)	13.0 (4.5)
Median	13.0	13.0	13.0	13.0	13.0
Range	0.0 - 21.0	0.0 - 21.0	1.0 - 21.0	5.0 - 21.0	0.0 - 21.0
Presence of angioedema*					
n	80	77	80	81	318
Yes	44 (55.0%)	35 (45.5%)	38 (47.5%)	34 (42.0%)	151 (47.5%)
No	36 (45.0%)	42 (54.5%)	42 (52.5%)	47 (58.0%)	167 (52.5%)
Weekly Proportion of Itch-Free Days*					
n	80	77	80	81	318
Mean (SD)	0.2% (1.6%)	0.4% (2.3%)	0.9% (4.2%)	0.2% (1.6%)	0.4% (2.6%)
Median	0.0%	0.0%	0.0%	0.0%	0.0%
Range	0.0% - 14.3%	0.0% - 14.3%	0.0% - 28.6%	0.0% - 14.3%	0.0% - 28.6%
Weekly Proportion of Hive-Free Days*					
n	80	77	80	81	318
Mean (SD)	0.4% (2.2%)	1.1% (5.6%)	0.9% (4.2%)	0.2% (1.6%)	0.6% (3.7%)
Median	0.0%	0.0%	0.0%	0.0%	0.0%
Range	0.0% - 14.3%	0.0% - 42.9%	0.0% - 28.6%	0.0% - 14.3%	0.0% - 42.9%
Weekly Proportion of Itch-Free and Hive-Free Days*					
n	80	77	80	81	318
Mean (SD)	0.2% (1.6%)	0.4% (2.3%)	0.7% (3.9%)	0.2% (1.6%)	0.4% (2.5%)
Median	0.0%	0.0%	0.0%	0.0%	0.0%
Range	0.0% - 14.3%	0.0% - 14.3%	0.0% - 28.6%	0.0% - 14.3%	0.0% - 28.6%

^Baseline in-clinic UAS is defined as the largest value among the Day -14 screening visit, Day -7 screening visit and Day 1 Visit.
*Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_bdc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.1/7
Baseline Disease Characteristics
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Number of Tablets/Week of Diphenhydramine (25mg)*					
n	80	77	80	81	318
Mean (SD)	8.1 (7.8)	7.5 (7.6)	7.6 (10.1)	7.5 (7.5)	7.7 (8.3)
Median	7.0	6.0	5.0	6.0	6.0
Range	0.0 - 32.0	0.0 - 36.0	0.0 - 57.0	0.0 - 30.0	0.0 - 57.0

^Baseline in-clinic UAS is defined as the largest value among the Day -14 screening visit, Day -7 screening visit and Day 1 Visit.
*Baseline weekly scores are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_bdc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.1/10
Targeted Medical History and Baseline Conditions
Modified Intention to Treat Patients

Diagnosis	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Allergic Rhinitis					
Ever	32 (40.0%)	29 (37.7%)	38 (47.5%)	34 (42.0%)	133 (41.8%)
Currently Active	32 (40.0%)	27 (35.1%)	35 (43.8%)	32 (39.5%)	126 (39.6%)
Angiodema					
Ever	30 (37.5%)	26 (33.8%)	31 (38.8%)	35 (43.2%)	122 (38.4%)
Currently Active	25 (31.3%)	23 (29.9%)	26 (32.5%)	26 (32.1%)	100 (31.4%)
Asthma					
Ever	16 (20.0%)	15 (19.5%)	23 (28.8%)	21 (25.9%)	75 (23.6%)
Currently Active	14 (17.5%)	12 (15.6%)	20 (25.0%)	16 (19.8%)	62 (19.5%)
Chronic Idiopathic Urticaria (Also Known As Chronic Spontaneous Urticaria)					
Ever	80 (100.0%)	77 (100.0%)	80 (100.0%)	81 (100.0%)	318 (100.0%)
Currently Active	80 (100.0%)	77 (100.0%)	80 (100.0%)	81 (100.0%)	318 (100.0%)
Coronary Artery Disease					
Ever	1 (1.3%)	3 (3.9%)	1 (1.3%)	2 (2.5%)	7 (2.2%)
Currently Active	1 (1.3%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	6 (1.9%)
Diabetes Mellitus					
Ever	3 (3.8%)	8 (10.4%)	6 (7.5%)	3 (3.7%)	20 (6.3%)
Currently Active	3 (3.8%)	8 (10.4%)	6 (7.5%)	2 (2.5%)	19 (6.0%)
Hypercholesterolemia					
Ever	7 (8.8%)	9 (11.7%)	9 (11.3%)	14 (17.3%)	39 (12.3%)
Currently Active	7 (8.8%)	9 (11.7%)	9 (11.3%)	11 (13.6%)	36 (11.3%)
Hypertension					
Ever	19 (23.8%)	22 (28.6%)	20 (25.0%)	19 (23.5%)	80 (25.2%)
Currently Active	19 (23.8%)	22 (28.6%)	20 (25.0%)	18 (22.2%)	79 (24.8%)
Myocardial Infarction					
Ever	2 (2.5%)	1 (1.3%)	(0.0%)	1 (1.2%)	4 (1.3%)
Currently Active	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)

Table 14.1/10
Targeted Medical History and Baseline Conditions
Modified Intention to Treat Patients

Diagnosis	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Parasitic Infections					
Ever	1 (1.3%)	(0.0%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
Currently Active	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Serum Sickness					
Ever	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
Currently Active	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
Stroke					
Ever	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
Currently Active	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Transient Ischemic Attack					
Ever	(0.0%)	1 (1.3%)	(0.0%)	2 (2.5%)	3 (0.9%)
Currently Active	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
- Any medication use -	80 (100.0%)	77 (100.0%)	80 (100.0%)	81 (100.0%)	318 (100.0%)
ANTIHISTAMINES					
-Overall-	80 (100.0%)	77 (100.0%)	79 (98.8%)	81 (100.0%)	317 (99.7%)
CETIRIZINE HYDROCHLORIDE	54 (67.5%)	53 (68.8%)	59 (73.8%)	63 (77.8%)	229 (72.0%)
FEXOFENADINE HYDROCHLORIDE	42 (52.5%)	36 (46.8%)	42 (52.5%)	46 (56.8%)	166 (52.2%)
LORATADINE	30 (37.5%)	35 (45.5%)	38 (47.5%)	24 (29.6%)	127 (39.9%)
DIPHENHYDRAMINE HYDROCHLORIDE	26 (32.5%)	22 (28.6%)	25 (31.3%)	21 (25.9%)	94 (29.6%)
LEVOCETIRIZINE HYDROCHLORIDE	18 (22.5%)	14 (18.2%)	23 (28.8%)	19 (23.5%)	74 (23.3%)
DESLORATADINE	12 (15.0%)	11 (14.3%)	14 (17.5%)	14 (17.3%)	51 (16.0%)
EBASTINE	7 (8.8%)	2 (2.6%)	5 (6.3%)	3 (3.7%)	17 (5.3%)
LEVOCETIRIZINE	3 (3.8%)	5 (6.5%)	4 (5.0%)	5 (6.2%)	17 (5.3%)
RUPATADINE	6 (7.5%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	12 (3.8%)
CLEMASTINE	1 (1.3%)	5 (6.5%)	2 (2.5%)	2 (2.5%)	10 (3.1%)
DIPHENHYDRAMINE NOS	2 (2.5%)	3 (3.9%)	3 (3.8%)	1 (1.2%)	9 (2.8%)
CHLORPHENIRAMINE MALEATE	1 (1.3%)	2 (2.6%)	2 (2.5%)	(0.0%)	5 (1.6%)
DIMETINDENE MALEATE	1 (1.3%)	2 (2.6%)	(0.0%)	1 (1.2%)	4 (1.3%)
AZELASTINE HYDROCHLORIDE	(0.0%)	(0.0%)	2 (2.5%)	1 (1.2%)	3 (0.9%)
BILASTINE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
CLEMASTINE FUMARATE	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
ACRIVASTINE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
CETIRIZINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
DIPHENHYDRAMINE HYDROCHLORIDE/ZINC ACETATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
FEXOFENADINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
KETOTIFEN FUMARATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
OLOPATADINE HYDROCHLORIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
TERFENADINE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
ANTAZOLINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ASTEMIZOLE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CARBINOXAMINE MALEATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DEXCHLORPHENIRAMINE MALEATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med_premed)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DIPHENHYDRAMINE DIACEFYLLINATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
EPINASTINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LORATADINE/PSEUDOEPHEDRINE SULFATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MEQUITAZINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MIZOLASTINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
OXOMEMAZINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
RUPATADINE FUMARATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	31 (38.8%)	21 (27.3%)	17 (21.3%)	24 (29.6%)	93 (29.2%)
RANITIDINE HYDROCHLORIDE	16 (20.0%)	15 (19.5%)	13 (16.3%)	12 (14.8%)	56 (17.6%)
RANITIDINE	13 (16.3%)	5 (6.5%)	3 (3.8%)	11 (13.6%)	32 (10.1%)
FAMOTIDINE	2 (2.5%)	5 (6.5%)	1 (1.3%)	2 (2.5%)	10 (3.1%)
CIMETIDINE	4 (5.0%)	1 (1.3%)	(0.0%)	2 (2.5%)	7 (2.2%)
IMMUNOSUPPRESSANTS					
-Overall-	9 (11.3%)	6 (7.8%)	6 (7.5%)	8 (9.9%)	29 (9.1%)
CICLOSPORIN	8 (10.0%)	6 (7.8%)	5 (6.3%)	7 (8.6%)	26 (8.2%)
MYCOPHENOLATE MOFETIL	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
AZATHIOPRINE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
TACROLIMUS	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
LEUKOTRIENE RECEPTOR ANTAGONISTS					
-Overall-	30 (37.5%)	18 (23.4%)	15 (18.8%)	20 (24.7%)	83 (26.1%)
MONTELUKAST SODIUM	27 (33.8%)	18 (23.4%)	15 (18.8%)	20 (24.7%)	80 (25.2%)
ZAFIRLUKAST	3 (3.8%)	(0.0%)	(0.0%)	(0.0%)	3 (0.9%)
ZILEUTON	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OTHER MEDICATIONS					
-Overall-	45 (56.3%)	35 (45.5%)	34 (42.5%)	34 (42.0%)	148 (46.5%)
HYDROXYZINE HYDROCHLORIDE	29 (36.3%)	19 (24.7%)	23 (28.8%)	26 (32.1%)	97 (30.5%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med_premed)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DOXEPIN HYDROCHLORIDE	9 (11.3%)	8 (10.4%)	11 (13.8%)	10 (12.3%)	38 (11.9%)
HYDROXYCHLOROQUINE SULFATE	2 (2.5%)	3 (3.9%)	4 (5.0%)	(0.0%)	9 (2.8%)
COLCHICINE	3 (3.8%)	(0.0%)	2 (2.5%)	(0.0%)	5 (1.6%)
DAPSONE	2 (2.5%)	(0.0%)	2 (2.5%)	1 (1.2%)	5 (1.6%)
EPINEPHRINE	1 (1.3%)	(0.0%)	2 (2.5%)	2 (2.5%)	5 (1.6%)
HYDROXYZINE NOS	1 (1.3%)	2 (2.6%)	2 (2.5%)	(0.0%)	5 (1.6%)
OMEPRAZOLE	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
BETAMETHASONE/DEXCHLORPHENIRAMINE MALEATE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
COLD AND SINUS REMEDIES	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
SULFASALAZINE	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
ADALIMUMAB	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
CHLOROQUINE PHOSPHATE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
DOXYCYCLINE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ETORICOXIB	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
OMALIZUMAB	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
OXATOMIDE	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
ACUPUNCTURE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGENIC EXTRACTS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ALOE/BIOFLAVONOIDS NOS/ENZYME NOS/LUTEOLIN/LYCOPENE/QUERCETIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ALPRAZOLAM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ARCTIUM LAPPA/GINGER/RUMEX CRISPUS/SARSAPARILLA	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ASCORBIC ACID	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ASCORBIC ACID/CHLORELLA/CYSTEINE HYDROCHLORIDE/ENZYMES/LACTOBACILLUS ACIDOPHIL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ASPARAGUS/BUCHU/GOLDENROD/JUNIPER	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ATENOLOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
AZITHROMYCIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BROMPHENIRAMINE MALEATE/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CALAMINE/ZINC OXIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CAMPHOR/MENTHOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med_premed)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
CEANORHUS AMERICANUS/STILLINGIA SYLVATICA/TRIFOLIUM PRATENSE/ZANTHOXYLUM	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CHLORPHENIRAMINE MALEATE/PHENYLEPHRINE HYDROCHLORIDE/SCOPOLAMINE METHYL NITRAT	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CODEINE PHOSPHATE/PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DANAZOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEFLAZACORT	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE/DOXYLAMINE SUCCINATE/PARACETAMOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ENZYMES/HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS/VITAMINS NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ESCITALOPRAM OXALATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GLOBULIN, IMMUNE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
GLYCERIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GRAPE/GREEN TEA/PINE/PYCNOGENOL/RESVERATROL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
IBUPROFEN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LANSOPRAZOLE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LEVOTHYROXINE SODIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
METHOTREXATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MIANSERIN HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PAROXETINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PROMETHAZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PROPRANOLOL HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PROTEASE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PYRIMETHAMINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SERTACONAZOLE NITRATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SERTRALINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TALC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med_premed)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ZINC OXIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STEROIDS					
-Overall-	34 (42.5%)	44 (57.1%)	40 (50.0%)	41 (50.6%)	159 (50.0%)
PREDNISONE	21 (26.3%)	29 (37.7%)	15 (18.8%)	24 (29.6%)	89 (28.0%)
METHYLPREDNISOLONE	8 (10.0%)	2 (2.6%)	4 (5.0%)	2 (2.5%)	16 (5.0%)
PREDNISOLONE	5 (6.3%)	2 (2.6%)	2 (2.5%)	5 (6.2%)	14 (4.4%)
MOMETASONE FUROATE	1 (1.3%)	3 (3.9%)	4 (5.0%)	2 (2.5%)	10 (3.1%)
HYDROCORTISONE	(0.0%)	2 (2.6%)	4 (5.0%)	3 (3.7%)	9 (2.8%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (2.5%)	3 (3.9%)	2 (2.5%)	2 (2.5%)	9 (2.8%)
CICLESONIDE	1 (1.3%)	3 (3.9%)	2 (2.5%)	2 (2.5%)	8 (2.5%)
TRIAMCINOLONE	2 (2.5%)	1 (1.3%)	3 (3.8%)	2 (2.5%)	8 (2.5%)
DEXAMETHASONE	(0.0%)	3 (3.9%)	2 (2.5%)	2 (2.5%)	7 (2.2%)
FLUTICASONE PROPIONATE	1 (1.3%)	4 (5.2%)	(0.0%)	2 (2.5%)	7 (2.2%)
FLUTICASONE FUROATE	(0.0%)	(0.0%)	2 (2.5%)	3 (3.7%)	5 (1.6%)
TRIAMCINOLONE ACETONIDE	1 (1.3%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
BECLOMETASONE DIPROPIONATE	(0.0%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
BETAMETHASONE	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
CLOBETASOL PROPIONATE	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
CORTICOSTEROID NOS	(0.0%)	(0.0%)	2 (2.5%)	1 (1.2%)	3 (0.9%)
DEXAMETHASONE SODIUM PHOSPHATE	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
PREDNISOLONE SODIUM METASULFOBENZOATE	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
BUDESONIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
CORTISONE ACETATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
DESONIDE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HYDROCORTISONE ACETATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
METHYLPREDNISOLONE ACEPONATE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
BETAMETHASONE/BETAMETHASONE SODIUM PHOSPHATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
HYDROCORTISONE SODIUM SUCCINATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
METHYLPREDNISOLONE ACETATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PREDNISOLONE ACETATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Table 14.1/8
Previous Medications for CIU
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
STEROID INJECTION NOS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STEROID NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications started at any time before first treatment date (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med_premed)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
For CIU					
- Any medication use -	80 (100.0%)	76 (98.7%)	80 (100.0%)	81 (100.0%)	317 (99.7%)
ADRENERGICS/SYMPATHOMIMETICS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
EPINEPHRINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIANXIETY AGENTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
HYDROXYZINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ANTIHISTAMINES					
-Overall-	80 (100.0%)	76 (98.7%)	78 (97.5%)	81 (100.0%)	315 (99.1%)
CETIRIZINE HYDROCHLORIDE	28 (35.0%)	31 (40.3%)	36 (45.0%)	31 (38.3%)	126 (39.6%)
FEXOFENADINE HYDROCHLORIDE	18 (22.5%)	19 (24.7%)	15 (18.8%)	26 (32.1%)	78 (24.5%)
LORATADINE	12 (15.0%)	11 (14.3%)	13 (16.3%)	5 (6.2%)	41 (12.9%)
LEVOCETIRIZINE HYDROCHLORIDE	10 (12.5%)	6 (7.8%)	8 (10.0%)	9 (11.1%)	33 (10.4%)
DESLORATADINE	6 (7.5%)	3 (3.9%)	6 (7.5%)	5 (6.2%)	20 (6.3%)
LEVOCETIRIZINE	1 (1.3%)	4 (5.2%)	(0.0%)	4 (4.9%)	9 (2.8%)
EBASTINE	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
RUPATADINE	3 (3.8%)	(0.0%)	(0.0%)	1 (1.2%)	4 (1.3%)
BILASTINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CETIRIZINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIMETINDENE MALEATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DIPHENHYDRAMINE DIACEFYLLINATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
RUPATADINE FUMARATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RANITIDINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
NON-STEROIDAL ANTI-INFLAMMATORIES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
IBUPROFEN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
STEROID/OTHER DRUG COMBINATIONS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BETAMETHASONE/DEXCHLORPHENIRAMINE MALEATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
STEROIDS					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
METHYLPREDNISOLONE ACEPONATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PREDNISOLONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Not for CIU					
- Any medication use -	50 (62.5%)	60 (77.9%)	65 (81.3%)	62 (76.5%)	237 (74.5%)
5-HT1 AGONISTS					
-Overall-	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
SUMATRIPTAN SUCCINATE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ELETRIPTAN HYDROBROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ZOLMITRIPTAN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
5-HT3 ANTAGONISTS					
-Overall-	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
ONDANSETRON	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ONDANSETRON HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ADRENERGICS/SYMPATHOMIMETICS					
-Overall-	1 (1.3%)	2 (2.6%)	(0.0%)	1 (1.2%)	4 (1.3%)
EPINEPHRINE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ALDOSTERONE ANTAGONISTS					
-Overall-	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
SPIRONOLACTONE	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
ALPHA-ADRENORECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TERAZOSIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
AMINOSALICYLATES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SULFASALAZINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANALGESIC/OTHER DRUG COMBINATIONS					
-Overall-	7 (8.8%)	2 (2.6%)	5 (6.3%)	3 (3.7%)	17 (5.3%)
ASPIRIN/CAFFEINE/PARACETAMOL	3 (3.8%)	1 (1.3%)	3 (3.8%)	1 (1.2%)	8 (2.5%)
HYDROCODONE TARTRATE/PARACETAMOL	4 (5.0%)	(0.0%)	2 (2.5%)	(0.0%)	6 (1.9%)
BUTALBITAL/CAFFEINE/PARACETAMOL	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANALGESIC/OTHER DRUG COMBINATIONS NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ASPIRIN/CITRIC ACID/SODIUM BICARBONATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE/PARACETAMOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANALGESICS					
-Overall-	5 (6.3%)	8 (10.4%)	7 (8.8%)	7 (8.6%)	27 (8.5%)
PARACETAMOL	3 (3.8%)	4 (5.2%)	5 (6.3%)	6 (7.4%)	18 (5.7%)
TRAMADOL	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
CODEINE PHOSPHATE/PARACETAMOL	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
TRAMADOL HYDROCHLORIDE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ANALGESIC NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROMORPHONE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OXYCODONE HYDROCHLORIDE/PARACETAMOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANDROGENS AND ANABOLIC STEROIDS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
TESTOSTERONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TESTOSTERONE CYPIONATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANGIOTENSIN II RECEPTOR ANTAGONISTS					
-Overall-	5 (6.3%)	3 (3.9%)	5 (6.3%)	4 (4.9%)	17 (5.3%)
LOSARTAN POTASSIUM	4 (5.0%)	(0.0%)	4 (5.0%)	1 (1.2%)	9 (2.8%)
VALSARTAN	(0.0%)	1 (1.3%)	(0.0%)	3 (3.7%)	4 (1.3%)
OLMESARTAN MEDOXOMIL	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)	3 (0.9%)
TELMISARTAN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS					
-Overall-	4 (5.0%)	6 (7.8%)	4 (5.0%)	3 (3.7%)	17 (5.3%)
ENALAPRIL MALEATE	1 (1.3%)	3 (3.9%)	1 (1.3%)	2 (2.5%)	7 (2.2%)
LISINOPRIL	(0.0%)	2 (2.6%)	3 (3.8%)	1 (1.2%)	6 (1.9%)
RAMIPRIL	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
BENAZEPRIL HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
QUINAPRIL HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANOREXIANTS AND CNS STIMULANTS					
-Overall-	(0.0%)	1 (1.3%)	6 (7.5%)	1 (1.2%)	8 (2.5%)
AMPHETAMINE ASPARTATE/AMPHETAMINE SULFATE/DEXTROAMPHETAMINE SACCHARATE/DEXT	(0.0%)	1 (1.3%)	3 (3.8%)	(0.0%)	4 (1.3%)
METHYLPHENIDATE HYDROCHLORIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
PHENTERMINE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ANTACIDS NEC					
-Overall-	3 (3.8%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	8 (2.5%)
CALCIUM CARBONATE	2 (2.5%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	7 (2.2%)
ALMAGATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIANEMIC AGENTS					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	5 (1.6%)
FERROUS SULFATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
FERROUS FUMARATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
IRON NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
POLYSACCHARIDE-IRON COMPLEX	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIANGINAL AGENTS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
HYDRALAZINE HYDROCHLORIDE/ISOSORBIDE DINITRATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ISOSORBIDE MONONITRATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
: Generated 25JAN13 14:31 Page 5 of 20

Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
NITROGLYCERIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIANXIETY AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
BUSPIRONE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYDROXYZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIARRHYTHMIC AGENTS NEC					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
PROPAFENONE HYDROCHLORIDE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ANTICOAGULANTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHENPROCOUMON	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTICONVULSANTS NEC					
-Overall-	3 (3.8%)	1 (1.3%)	5 (6.3%)	4 (4.9%)	13 (4.1%)
GABAPENTIN	1 (1.3%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	5 (1.6%)
PREGABALIN	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
LEVETIRACETAM	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
TOPIRAMATE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
CARBAMAZEPINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LAMOTRIGINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIDEPRESSANTS NEC					
-Overall-	4 (5.0%)	6 (7.8%)	7 (8.8%)	4 (4.9%)	21 (6.6%)
VENLAFAXINE HYDROCHLORIDE	1 (1.3%)	3 (3.9%)	4 (5.0%)	(0.0%)	8 (2.5%)
BUPROPION HYDROCHLORIDE	3 (3.8%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	7 (2.2%)
TRAZODONE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	3 (3.7%)	4 (1.3%)
ATOMOXETINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DESVENLAFAXINE SUCCINATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANTIDIARRHEALS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LOPERAMIDE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIEMETICS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
MECLIZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
METOCLOPRAMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIFUNGAL AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
ECONAZOLE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
KETOCONAZOLE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NYSTATIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIGLAUCOMA AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BIMATOPROST	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIGOUT AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ALLOPURINOL	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANTIHISTAMINES					
-Overall-	1 (1.3%)	1 (1.3%)	6 (7.5%)	1 (1.2%)	9 (2.8%)
AZELASTINE HYDROCHLORIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
OLOPATADINE HYDROCHLORIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
EPINASTINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
FEXOFENADINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OXOMEMAZINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANTIHYPERTENSIVE AGENTS NEC					
-Overall-	2 (2.5%)	2 (2.6%)	2 (2.5%)	3 (3.7%)	9 (2.8%)
CLONIDINE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
HYDROCHLOROTHIAZIDE/LISINOPRIL	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HYDROCHLOROTHIAZIDE/VALSARTAN	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
AMLODIPINE BESILATE/VALSARTAN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ATENOLOL/CHLORTHALIDONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROCHLOROTHIAZIDE/METOPROLOL TARTRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIMALARIAL AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROXYCHLOROQUINE SULFATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIMIGRAINE AGENTS NEC					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
DICHLORALPHENAZONE/ISOMETHEPTENE MUCATE/PARACETAMOL	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANTISPASMODICS AND ANTICHOLINERGICS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
DICYCLOVERINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
SCOPOLAMINE BUTYLBROMIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SOLIFENACIN SUCCINATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TOLTERODINE TARTRATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIVIRAL AGENTS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
ACICLOVIR	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
BENZODIAZEPINES					
-Overall-	7 (8.8%)	3 (3.9%)	4 (5.0%)	8 (9.9%)	22 (6.9%)
ALPRAZOLAM	2 (2.5%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	8 (2.5%)

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Table 14.1/9.1
Concomitant Medications: Baseline
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Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DIAZEPAM	2 (2.5%)	(0.0%)	1 (1.3%)	3 (3.7%)	6 (1.9%)
LORAZEPAM	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
CLONAZEPAM	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
CLORAZEPATE DIPOTASSIUM	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FLURAZEPAM HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TETRAZEPAM	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BETA-ADRENOCEPTOR BLOCKING AGENTS					
-Overall-	5 (6.3%)	8 (10.4%)	4 (5.0%)	6 (7.4%)	23 (7.2%)
METOPROLOL NOS	(0.0%)	2 (2.6%)	(0.0%)	2 (2.5%)	4 (1.3%)
PROPRANOLOL HYDROCHLORIDE	(0.0%)	2 (2.6%)	(0.0%)	2 (2.5%)	4 (1.3%)
ATENOLOL	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
METOPROLOL SUCCINATE	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
NEBIVOLOL HYDROCHLORIDE	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)	3 (0.9%)
BISOPROLOL	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BISOPROLOL FUMARATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
LABETALOL HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METOPROLOL TARTRATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
BIGUANIDES					
-Overall-	2 (2.5%)	5 (6.5%)	4 (5.0%)	1 (1.2%)	12 (3.8%)
METFORMIN HYDROCHLORIDE	2 (2.5%)	5 (6.5%)	4 (5.0%)	1 (1.2%)	12 (3.8%)
BISPHOSPHONATES					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ALENDRONATE SODIUM	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
BRONCHODILATORS AND ANTIASTHMATICS					
-Overall-	11 (13.8%)	8 (10.4%)	19 (23.8%)	10 (12.3%)	48 (15.1%)
SALBUTAMOL/SALBUTAMOL SULFATE	9 (11.3%)	7 (9.1%)	15 (18.8%)	7 (8.6%)	38 (11.9%)
BUDESONIDE/FORMOTEROL FUMARATE	1 (1.3%)	1 (1.3%)	4 (5.0%)	3 (3.7%)	9 (2.8%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	2 (2.5%)	(0.0%)	5 (6.3%)	2 (2.5%)	9 (2.8%)
LEVOSALBUTAMOL HYDROCHLORIDE/LEVOSALBUTAMOL TARTRATE	(0.0%)	(0.0%)	2 (2.5%)	1 (1.2%)	3 (0.9%)
FORMOTEROL FUMARATE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
IPRATROPIUM BROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LEVALBUTEROL TARTRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPROTEROL HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SODIUM CROMOGLYCATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TIOTROPIUM BROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CALCIUM CHANNEL BLOCKING AGENTS					
-Overall-	6 (7.5%)	6 (7.8%)	3 (3.8%)	5 (6.2%)	20 (6.3%)
AMLODIPINE	3 (3.8%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	7 (2.2%)
AMLODIPINE BESILATE	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
VERAPAMIL HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
FELODIPINE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
LACIDIPINE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
LERCANIDIPINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
CALCIUM COMPOUNDS AND REGULATORS					
-Overall-	(0.0%)	4 (5.2%)	5 (6.3%)	6 (7.4%)	15 (4.7%)
CALCIUM NOS	(0.0%)	(0.0%)	4 (5.0%)	3 (3.7%)	7 (2.2%)
CALCIUM NOS/CHOLECALCIFEROL	(0.0%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
CALCIUM ACETATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CALCIUM CARBONATE/CHOLECALCIFEROL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CALCIUM NOS/GENERIC COMPONENT(S) NOT KNOWN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
COLD AND SINUS REMEDIES					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
COLD AND SINUS REMEDIES	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
GUAIFENESIN/PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
COUGH PREPARATIONS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
GUAIFENESIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
COX-2 INHIBITORS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
CELECOXIB	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
DIURETICS NEC					
-Overall-	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)	3 (0.9%)
INDAPAMIDE	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
AMILORIDE HYDROCHLORIDE/HYDROCHLOROTHIAZIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
FIBRATES					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FENOFIBRATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FOLIC ACID AND DERIVATIVES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
FOLIC ACID	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS					
-Overall-	9 (11.3%)	8 (10.4%)	4 (5.0%)	2 (2.5%)	23 (7.2%)
FISH OIL	4 (5.0%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	8 (2.5%)
DOCOSAHEXAENOIC ACID/EICOSAPENTAENOIC ACID	(0.0%)	5 (6.5%)	(0.0%)	(0.0%)	5 (1.6%)
GLUCOSAMINE NOS	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
PROBIOTIC SUPPLEMENT NOS	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ALOE/BLACK WALNUT/CASCARA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SAGRADA/GRAPE/RHUBARB/RUMEX CRISPUS/SENNA/SLIPPER					
CHONDROITIN SULFATE/GLUCOSAMINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CRANBERRY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DIETARY FIBER	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS/MINERALS NOS/MULTIVITAMINS NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MELATONIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SACCHAROMYCES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SAW PALMETTO	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SEA BUCKTHORN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
VINEGAR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	4 (5.0%)	6 (7.8%)	2 (2.5%)	4 (4.9%)	16 (5.0%)
RANITIDINE HYDROCHLORIDE	2 (2.5%)	1 (1.3%)	1 (1.3%)	4 (4.9%)	8 (2.5%)
RANITIDINE	2 (2.5%)	3 (3.9%)	1 (1.3%)	(0.0%)	6 (1.9%)
FAMOTIDINE	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
HYPOGLYCEMICS NEC					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SAXAGLIPTIN HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNOMODULATORS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
INTERFERON BETA-1A	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INTERFERON BETA-1B	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
INSULINS					
-Overall-	(0.0%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
INSULIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
INSULIN ASPART	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INSULIN GLULISINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
INSULIN HUMAN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LISPRO INSULIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
NPH HUMAN INSULIN ISOPHANE SUSPENSION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ION EXCHANGE RESINS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
COLESEVELAM HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LAXATIVES AND STOOL SOFTENERS					
-Overall-	1 (1.3%)	(0.0%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
DOCUSATE SODIUM	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
LAXATIVES AND STOOL SOFTENERS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
STOOL SOFTENER NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOTRIENE RECEPTOR ANTAGONISTS					
-Overall-	2 (2.5%)	(0.0%)	4 (5.0%)	1 (1.2%)	7 (2.2%)
MONTELUKAST SODIUM	2 (2.5%)	(0.0%)	4 (5.0%)	1 (1.2%)	7 (2.2%)
LIPID REGULATING AGENTS NEC					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EZETIMIBE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LOOP DIURETICS					
-Overall-	1 (1.3%)	2 (2.6%)	(0.0%)	1 (1.2%)	4 (1.3%)
TORASEMIDE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
FUROSEMIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MACROLIDE ANTIBIOTICS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
AZITHROMYCIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MISCELLANEOUS ANTIMICROBIALS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

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Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUPIROCIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MISCELLANEOUS GASTROINTESTINAL AGENTS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
ALVERINE CITRATE/SIMETHICONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LUBIPROSTONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SIMETHICONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MUCOSAL PROTECTANTS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
BISMUTH SUBSALICYLATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SUCRALFATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE RELAXANTS					
-Overall-	1 (1.3%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	6 (1.9%)
CARISOPRODOL	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CYCLOBENZAPRINE HYDROCHLORIDE	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
BACLOFEN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TIZANIDINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NITROFURANS					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
NITROFURANTOIN	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
NON DRUG THERAPIES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
RESPIRATORY TREATMENTS AND DEVICES	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
NON-STEROIDAL ANTI-INFLAMMATORIES					
-Overall-	13 (16.3%)	8 (10.4%)	8 (10.0%)	7 (8.6%)	36 (11.3%)
IBUPROFEN	4 (5.0%)	8 (10.4%)	6 (7.5%)	5 (6.2%)	23 (7.2%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
NAPROXEN SODIUM	2 (2.5%)	(0.0%)	2 (2.5%)	3 (3.7%)	7 (2.2%)
DICLOFENAC SODIUM	3 (3.8%)	(0.0%)	(0.0%)	1 (1.2%)	4 (1.3%)
DICLOFENAC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DICLOFENAC EPOLAMINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIPYRONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ETODOLAC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MELOXICAM	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TIAPROFENIC ACID	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OPIOID ANALGESICS					
-Overall-	(0.0%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	5 (1.6%)
HYDROCODONE NOS	(0.0%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	5 (1.6%)
OPIOID ANTAGONISTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BUPRENORPHINE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PENICILLINS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
AMOXICILLIN/CLAVULANATE POTASSIUM	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PERIPHERAL AND CEREBRAL VASCULAR AGENTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DIOSMIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PHARMACEUTIC AIDS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
POLYETHYLENE GLYCOL	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
PHARMACOTHERAPEUTIC CLASS(ES) NOT KNOWN					
-Overall-	(0.0%)	2 (2.6%)	2 (2.5%)	(0.0%)	4 (1.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERIC COMPONENT(S) NOT KNOWN	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)	3 (0.9%)
CONTRACEPTIVE NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PHENOTHIAZINES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRIFLUOPERAZINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PHOSPHODIESTERASE INHIBITORS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SILDENAFIL CITRATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PLATELET AGGREGATION INHIBITORS					
-Overall-	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
CLOPIDOGREL BISULFATE	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
PROTON PUMP INHIBITORS					
-Overall-	9 (11.3%)	7 (9.1%)	9 (11.3%)	11 (13.6%)	36 (11.3%)
OMEPRAZOLE	2 (2.5%)	4 (5.2%)	5 (6.3%)	6 (7.4%)	17 (5.3%)
ESOMEPRAZOLE MAGNESIUM	1 (1.3%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	5 (1.6%)
LANSOPRAZOLE	1 (1.3%)	(0.0%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
PANTOPRAZOLE	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
PANTOPRAZOLE SODIUM	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
RABEPRAZOLE SODIUM	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
DEXLANSOPRAZOLE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SALICYLATES					
-Overall-	3 (3.8%)	3 (3.9%)	2 (2.5%)	4 (4.9%)	12 (3.8%)
ASPIRIN	3 (3.8%)	3 (3.9%)	2 (2.5%)	4 (4.9%)	12 (3.8%)
SEDATIVES AND HYPNOTICS					
-Overall-	4 (5.0%)	5 (6.5%)	1 (1.3%)	(0.0%)	10 (3.1%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ZOLPIDEM TARTRATE	2 (2.5%)	5 (6.5%)	1 (1.3%)	(0.0%)	8 (2.5%)
ESZOPICLONE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS					
-Overall-	8 (10.0%)	6 (7.8%)	5 (6.3%)	5 (6.2%)	24 (7.5%)
SERTRALINE HYDROCHLORIDE	4 (5.0%)	1 (1.3%)	2 (2.5%)	2 (2.5%)	9 (2.8%)
CITALOPRAM	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
CITALOPRAM HYDROBROMIDE	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
DULOXETINE HYDROCHLORIDE	(0.0%)	3 (3.9%)	(0.0%)	(0.0%)	3 (0.9%)
ESCITALOPRAM OXALATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
FLUOXETINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PAROXETINE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
SEX HORMONES					
-Overall-	8 (10.0%)	11 (14.3%)	18 (22.5%)	17 (21.0%)	54 (17.0%)
DESOGESTREL/ETHINYL ESTRADIOL	1 (1.3%)	1 (1.3%)	2 (2.5%)	4 (4.9%)	8 (2.5%)
ESTRADIOL	1 (1.3%)	(0.0%)	4 (5.0%)	3 (3.7%)	8 (2.5%)
ETHINYL ESTRADIOL/NORGESTIMATE	1 (1.3%)	2 (2.6%)	3 (3.8%)	1 (1.2%)	7 (2.2%)
DROSPIRENONE/ETHINYL ESTRADIOL	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
ETHINYL ESTRADIOL/LEVONORGESTREL	1 (1.3%)	1 (1.3%)	2 (2.5%)	(0.0%)	4 (1.3%)
ETHINYL ESTRADIOL/GESTODENE	(0.0%)	1 (1.3%)	(0.0%)	2 (2.5%)	3 (0.9%)
ETHINYL ESTRADIOL/NORETHISTERONE ACETATE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
ETHINYL ESTRADIOL/NORGESTREL	(0.0%)	2 (2.6%)	(0.0%)	1 (1.2%)	3 (0.9%)
MEDROXYPROGESTERONE ACETATE	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
DESOGESTREL	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ETHINYL ESTRADIOL/FERROUS FUMARATE/NORETHISTERONE ACETATE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ETONOGESTREL	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
DIENOGEST/ESTRADIOL VALERATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ESTROGENS, CONJUGATED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ETHINYL ESTRADIOL/ETONOGESTREL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ETHINYL ESTRADIOL/NORETHISTERONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LEVONORGESTREL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PROGESTERONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STATINS					
-Overall-	7 (8.8%)	7 (9.1%)	5 (6.3%)	6 (7.4%)	25 (7.9%)
SIMVASTATIN	4 (5.0%)	2 (2.6%)	1 (1.3%)	3 (3.7%)	10 (3.1%)
ATORVASTATIN CALCIUM	1 (1.3%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
ROSUVASTATIN	2 (2.5%)	2 (2.6%)	(0.0%)	1 (1.2%)	5 (1.6%)
PRAVASTATIN SODIUM	(0.0%)	(0.0%)	3 (3.8%)	(0.0%)	3 (0.9%)
LOVASTATIN	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
STEROIDS					
-Overall-	4 (5.0%)	7 (9.1%)	11 (13.8%)	9 (11.1%)	31 (9.7%)
MOMETASONE FUROATE	1 (1.3%)	1 (1.3%)	4 (5.0%)	2 (2.5%)	8 (2.5%)
CICLESONIDE	1 (1.3%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	7 (2.2%)
FLUTICASONE PROPIONATE	1 (1.3%)	4 (5.2%)	(0.0%)	2 (2.5%)	7 (2.2%)
FLUTICASONE FUROATE	(0.0%)	(0.0%)	2 (2.5%)	2 (2.5%)	4 (1.3%)
BECLOMETASONE DIPROPIONATE	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
BUDESONIDE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
CLOBETASOL PROPIONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
METHYLPREDNISOLONE SODIUM SUCCINATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TRIAMCINOLONE ACETONIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SULFONYLUREAS					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
GLIMEPIRIDE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
SUPPLEMENTS					
-Overall-	4 (5.0%)	7 (9.1%)	3 (3.8%)	3 (3.7%)	17 (5.3%)
SODIUM CHLORIDE	1 (1.3%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	6 (1.9%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
POTASSIUM CHLORIDE	1 (1.3%)	3 (3.9%)	(0.0%)	(0.0%)	4 (1.3%)
MAGNESIUM ASPARTATE/POTASSIUM ASPARTATE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
MAGNESIUM NOS	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
GLUCAGON	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
POTASSIUM NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TETRACYCLINES					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
DOXYCYCLINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MINOCYCLINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
THIAZIDE DIURETICS					
-Overall-	2 (2.5%)	3 (3.9%)	2 (2.5%)	5 (6.2%)	12 (3.8%)
HYDROCHLOROTHIAZIDE	2 (2.5%)	3 (3.9%)	2 (2.5%)	5 (6.2%)	12 (3.8%)
THYROID HORMONES					
-Overall-	8 (10.0%)	7 (9.1%)	6 (7.5%)	10 (12.3%)	31 (9.7%)
LEVOTHYROXINE SODIUM	8 (10.0%)	7 (9.1%)	6 (7.5%)	10 (12.3%)	31 (9.7%)
TRICYCLIC ANTIDEPRESSANTS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
AMITRIPTYLINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
OPIPRAMOL HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VACCINES, TOXOIDS AND SEROLOGIC AGENTS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
ALLERGENIC EXTRACTS	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
BOTULINUM TOXIN TYPE A	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS AND MINERALS					
-Overall-	10 (12.5%)	13 (16.9%)	9 (11.3%)	19 (23.5%)	51 (16.0%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.1
Concomitant Medications: Baseline
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
MULTIVITAMINS NOS	3 (3.8%)	7 (9.1%)	4 (5.0%)	8 (9.9%)	22 (6.9%)
VITAMIN D NOS	3 (3.8%)	3 (3.9%)	3 (3.8%)	4 (4.9%)	13 (4.1%)
ASCORBIC ACID	2 (2.5%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	6 (1.9%)
MINERALS NOS/MULTIVITAMINS NOS	2 (2.5%)	(0.0%)	(0.0%)	3 (3.7%)	5 (1.6%)
CYANOCOBALAMIN	(0.0%)	1 (1.3%)	(0.0%)	3 (3.7%)	4 (1.3%)
CHOLECALCIFEROL	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
VITAMIN B NOS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
VITAMIN E	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
CALCIUM LACTATE/CHOLECALCIFEROL/MAGNESIUM LACTATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CHROMIUM PICOLINATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
IRON NOS/MULTIVITAMINS NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VITAMIN B COMPLEX	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS AND MINERALS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications which were started or ongoing on the date of the first treatment (Day 1).

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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
For CIU					
- Any medication use -	19 (23.8%)	16 (20.8%)	16 (20.0%)	8 (9.9%)	59 (18.6%)
ANTIANXIETY AGENTS					
-Overall-	(0.0%)	1 (1.3%)	4 (5.0%)	1 (1.2%)	6 (1.9%)
HYDROXYZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	4 (5.0%)	1 (1.2%)	6 (1.9%)
ANTIHISTAMINES					
-Overall-	11 (13.8%)	13 (16.9%)	10 (12.5%)	5 (6.2%)	39 (12.3%)
CETIRIZINE HYDROCHLORIDE	3 (3.8%)	4 (5.2%)	4 (5.0%)	1 (1.2%)	12 (3.8%)
FEXOFENADINE HYDROCHLORIDE	1 (1.3%)	3 (3.9%)	6 (7.5%)	2 (2.5%)	12 (3.8%)
DESLORATADINE	2 (2.5%)	4 (5.2%)	1 (1.3%)	1 (1.2%)	8 (2.5%)
RUPATADINE	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
LORATADINE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
CLEMASTINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DEXCHLORPHENIRAMINE MALEATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIMETINDENE MALEATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FEXOFENADINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHENIRAMINE MALEATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RUPATADINE FUMARATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTILEPROSY AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DAPSONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
COLD AND SINUS REMEDIES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DIPHENHYDRAMINE CITRATE/IBUPROFEN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	4 (5.0%)	(0.0%)	1 (1.3%)	(0.0%)	5 (1.6%)
RANITIDINE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
RANITIDINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
NIZATIDINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNOSUPPRESSANTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CICLOSPORIN	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
LEUKOTRIENE RECEPTOR ANTAGONISTS					
-Overall-	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
MONTELUKAST SODIUM	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
STEROIDS					
-Overall-	8 (10.0%)	3 (3.9%)	5 (6.3%)	2 (2.5%)	18 (5.7%)
PREDNISONE	8 (10.0%)	2 (2.6%)	3 (3.8%)	1 (1.2%)	14 (4.4%)
BETAMETHASONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CLOBETASOL PROPIONATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CORTISONE ACETATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
FLUOCINONIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROCORTISONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
METHYLPREDNISOLONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PREDNISOLONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TRICYCLIC ANTIDEPRESSANTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DOXEPIN HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Not for CIU					
- Any medication use -	38 (47.5%)	37 (48.1%)	45 (56.3%)	41 (50.6%)	161 (50.6%)
5-HT3 ANTAGONISTS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
ONDANSETRON HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
ADRENERGICS/SYMPATHOMIMETICS					
-Overall-	4 (5.0%)	5 (6.5%)	1 (1.3%)	(0.0%)	10 (3.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.5%)	3 (3.9%)	(0.0%)	(0.0%)	5 (1.6%)
EPINEPHRINE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
OXYMETAZOLINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
NAPHAZOLINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TETRYZOLINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ALPHA-ADRENORECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DOXAZOSIN MESILATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
AMINOGLYCOSIDE ANTIMICROBIALS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FRAMYCETIN SULFATE/THENOIC ACID	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANALGESIC/OTHER DRUG COMBINATIONS					
-Overall-	2 (2.5%)	2 (2.6%)	4 (5.0%)	3 (3.7%)	11 (3.5%)
HYDROCODONE TARTRATE/PARACETAMOL	2 (2.5%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	8 (2.5%)
ASPIRIN/CAFFEINE/PARACETAMOL	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ASCORBIC ACID/PARACETAMOL/PHENIRAMINE MALEATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANALGESICS					
-Overall-	5 (6.3%)	8 (10.4%)	10 (12.5%)	9 (11.1%)	32 (10.1%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
PARACETAMOL	3 (3.8%)	7 (9.1%)	6 (7.5%)	3 (3.7%)	19 (6.0%)
OXYCODONE HYDROCHLORIDE/PARACETAMOL	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
TRAMADOL	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
PHENAZOPYRIDINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CODEINE PHOSPHATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CODEINE PHOSPHATE/PARACETAMOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FENTANYL CITRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROMORPHONE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OXYCODONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PARACETAMOL/TRAMADOL HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PETHIDINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PIRITRAMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REMIFENTANIL HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TRAMADOL HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANGIOTENSIN II RECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
OLMESARTAN MEDOXOMIL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VALSARTAN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS					
-Overall-	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)	3 (0.9%)
ENALAPRIL MALEATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LISINOPRIL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
QUINAPRIL HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANOREXIANTS AND CNS STIMULANTS					
-Overall-	1 (1.3%)	(0.0%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
PHENTERMINE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
DIETHYLPROPION HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHENDIMETRAZINE TARTRATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANTACIDS NEC					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
CALCIUM CARBONATE	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
ANTIANEMIC AGENTS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
FERROUS GLYCINE SULFATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
FERROUS SULFATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIANGINAL AGENTS NEC					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
ISOSORBIDE DINITRATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NITROGLYCERIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIANXIETY AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BUSPIRONE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTICOAGULANTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ENOXAPARIN SODIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTICONVULSANTS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
TOPIRAMATE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
GABAPENTIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIDEPRESSANTS NEC					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
BUPROPION HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRAZODONE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANTIEMETICS NEC					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
METOCLOPRAMIDE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANTIFUNGAL AGENTS					
-Overall-	(0.0%)	1 (1.3%)	4 (5.0%)	(0.0%)	5 (1.6%)
FLUCONAZOLE	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
CLOTRIMAZOLE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MICONAZOLE NITRATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
NYSTATIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TERBINAFINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIGOUT AGENTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ALLOPURINOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIHISTAMINES					
-Overall-	1 (1.3%)	2 (2.6%)	2 (2.5%)	2 (2.5%)	7 (2.2%)
AZELASTINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
ANTAZOLINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DESLORATADINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OLOPATADINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANTIHYPERTENSIVE AGENTS NEC					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
HYDROCHLOROTHIAZIDE/OLMESARTAN MEDOXOMIL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIMICROBIAL/OTHER DRUG COMBINATIONS					
-Overall-	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
CLINDAMYCIN PHOSPHATE/TRETINOIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DEXAMETHASONE/TOBRAMYCIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NYSTATIN/TRIAMCINOLONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTISEPTICS AND DISINFECTANTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHENOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTISPASMODICS AND ANTICHOLINERGICS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ATROPINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTITHYROID AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
THIAMAZOLE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTITRICHOMONAL AGENTS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
METRONIDAZOLE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
ANTIVIRAL AGENTS NEC					
-Overall-	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
ACICLOVIR	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
BENZODIAZEPINES					
-Overall-	1 (1.3%)	(0.0%)	4 (5.0%)	1 (1.2%)	6 (1.9%)
DIAZEPAM	(0.0%)	(0.0%)	3 (3.8%)	1 (1.2%)	4 (1.3%)
MIDAZOLAM HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TETRAZEPAM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
BETA-ADRENOCEPTOR BLOCKING AGENTS					
-Overall-	(0.0%)	(0.0%)	2 (2.5%)	2 (2.5%)	4 (1.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ACEBUTOLOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BISOPROLOL FUMARATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LABETALOL HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEBIVOLOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
BIGUANIDES					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
METFORMIN HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
BRONCHODILATORS AND ANTIASTHMATICS					
-Overall-	4 (5.0%)	5 (6.5%)	6 (7.5%)	1 (1.2%)	16 (5.0%)
SALBUTAMOL/SALBUTAMOL SULFATE	2 (2.5%)	3 (3.9%)	5 (6.3%)	(0.0%)	10 (3.1%)
LEVOSALBUTAMOL HYDROCHLORIDE/LEVOSALBUTAMOL TARTRATE	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
BUDESONIDE/FORMOTEROL FUMARATE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
AMINOPHYLLINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BECLOMETASONE DIPROPIONATE/FORMOTEROL FUMARATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
IPRATROPIUM BROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SODIUM CROMOGLYCATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CALCIUM CHANNEL BLOCKING AGENTS					
-Overall-	(0.0%)	1 (1.3%)	3 (3.8%)	1 (1.2%)	5 (1.6%)
VERAPAMIL HYDROCHLORIDE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
AMLODIPINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
AMLODIPINE BESILATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LERCANIDIPINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CEPHALOSPORIN ANTIBIOTICS					
-Overall-	1 (1.3%)	5 (6.5%)	4 (5.0%)	1 (1.2%)	11 (3.5%)
CEPHALEXIN	(0.0%)	4 (5.2%)	1 (1.3%)	(0.0%)	5 (1.6%)
CEFDINIR	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
CEFIXIME	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
CEFTRIAXONE SODIUM	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CEFPODOXIME PROXETIL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CEFPROZIL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CEFUROXIME	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CEFUROXIME AXETIL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
COLD AND SINUS REMEDIES					
-Overall-	6 (7.5%)	7 (9.1%)	6 (7.5%)	1 (1.2%)	20 (6.3%)
COLD AND SINUS REMEDIES	3 (3.8%)	2 (2.6%)	4 (5.0%)	(0.0%)	9 (2.8%)
DEXTROMETHORPHAN HYDROBROMIDE/DOXYLAMINE SUCCINATE/PARACETAMOL	(0.0%)	5 (6.5%)	3 (3.8%)	(0.0%)	8 (2.5%)
IBUPROFEN/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ASPIRIN/CHLORPHENIRAMINE MALEATE/DEXTROMETHORPHAN HYDROBROMIDE/PHENYLEPHRIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CHLORPHENIRAMINE MALEATE/DEXTROMETHORPHAN HYDROBROMIDE/PARACETAMOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CODEINE/COLD AND SINUS REMEDIES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE/GUAIFENESIN/PHENYLEPHRINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PARACETAMOL/PHENIRAMINE MALEATE/PHENYLEPHRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
COUGH PREPARATIONS					
-Overall-	2 (2.5%)	2 (2.6%)	5 (6.3%)	(0.0%)	9 (2.8%)
GUAIFENESIN	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
AMBROXOL HYDROCHLORIDE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
BENZONATATE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
CODEINE PHOSPHATE/GUAIFENESIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEXTROMETHORPHAN HYDROBROMIDE/GUAIFENESIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
HERB(S) NOS/MENTHOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
COX-2 INHIBITORS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CELECOXIB	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CYTOTOXIC ANTIBIOTICS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ACETOMYCIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DERMATOLOGIC AGENTS					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
ADAPALENE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROQUINONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ISOTRETINOIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIAGNOSTIC AIDS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
GADOLINIUM	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
IOVERSOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DIURETICS NEC					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
AMILORIDE HYDROCHLORIDE/HYDROCHLOROTHIAZIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ENZYMES					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
AMYLASE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FIBRATES					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
GEMFIBROZIL	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
GENERAL ANESTHETICS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROPOFOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HEMOSTATICS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PHYTOMENADIONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS					
-Overall-	5 (6.3%)	3 (3.9%)	2 (2.5%)	3 (3.7%)	13 (4.1%)
MELATONIN	2 (2.5%)	2 (2.6%)	(0.0%)	(0.0%)	4 (1.3%)
FISH OIL	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BONESET/CELLULOSE/LACTOBACILLUS SPOROGENES/LACTOSE/MALTODEXTRIN/MISTLETOE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CAJUPUT OIL/CAMPHOR/CINNAMON OIL/CLOVE OIL/MENTHOL/PEPPERMINT OIL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CALCIUM CARBONATE/DEHYDROEPIANDROSTERONE/FOLIC ACID/HERBAL,HOMEOPATHIC,& DI	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LINSEED	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MYRTLE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PROBIOTIC SUPPLEMENT NOS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VINPOCETINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
FAMOTIDINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
RANITIDINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
HYPOGLYCEMICS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
LINAGLIPTIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LIRAGLUTIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INSULINS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
INSULIN	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
INSULIN (SUSPENSION), ISOPHANE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
INSULIN HUMAN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LAXATIVES AND STOOL SOFTENERS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DOCUSATE SODIUM	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOTRIENE RECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
MONTELUKAST SODIUM	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
LINCOMYCIN ANTIBIOTICS					
-Overall-	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
CLINDAMYCIN	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)	3 (0.9%)
LOCAL ANESTHETICS					
-Overall-	2 (2.5%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	7 (2.2%)
LIDOCAINE	1 (1.3%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	6 (1.9%)
BUPIVACAINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
LOOP DIURETICS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
FUROSEMIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
TORASEMIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MACROLIDE ANTIBIOTICS					
-Overall-	7 (8.8%)	4 (5.2%)	8 (10.0%)	2 (2.5%)	21 (6.6%)
AZITHROMYCIN	6 (7.5%)	3 (3.9%)	8 (10.0%)	2 (2.5%)	19 (6.0%)
CLARITHROMYCIN	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
MISCELLANEOUS ANTIMICROBIALS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
FOSFOMYCIN TROMETHAMINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
NIFUROXAZIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MISCELLANEOUS GASTROINTESTINAL AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CISAPRIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MUCOSAL PROTECTANTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BISMUTH SUBSALICYLATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE RELAXANTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	3 (3.7%)	4 (1.3%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
CARISOPRODOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METAXALONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NITROFURANS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
NITROFURANTOIN	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
NON DRUG THERAPIES					

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
CONTRACEPTIVE DEVICES	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRANSCUTANEOUS NERVE STIMULATOR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NON-STEROIDAL ANTI-INFLAMMATORIES					
-Overall-	4 (5.0%)	4 (5.2%)	7 (8.8%)	10 (12.3%)	25 (7.9%)
IBUPROFEN	3 (3.8%)	3 (3.9%)	4 (5.0%)	5 (6.2%)	15 (4.7%)
KETOROLAC TROMETAMOL	(0.0%)	(0.0%)	1 (1.3%)	3 (3.7%)	4 (1.3%)
MELOXICAM	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
NAPROXEN	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
NAPROXEN SODIUM	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
DICLOFENAC SODIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DIPYRONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INDOMETACIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
KETOPROFEN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
NIMESULIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
OPHTHALMIC PREPARATIONS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ARTIFICIAL TEARS NOS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EYE DROPS NOS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OPIOID ANALGESICS					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
HYDROCODONE NOS	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
OPIOID ANTAGONISTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BUPRENORPHINE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PENICILLINS					

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Overall-	6 (7.5%)	2 (2.6%)	2 (2.5%)	4 (4.9%)	14 (4.4%)
AMOXICILLIN	5 (6.3%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	9 (2.8%)
AMOXICILLIN/CLAVULANATE POTASSIUM	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
AMOXICILLIN SODIUM/AMOXICILLIN TRIHYDRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
AMPICILLIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PENICILLIN V POTASSIUM	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PHARMACEUTIC AIDS					
-Overall-	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
MENTHOL	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
SODIUM HYALURONATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
PHARMACOTHERAPEUTIC CLASS(ES) NOT KNOWN					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
GENERIC COMPONENT(S) NOT KNOWN	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PROSTAGLANDINS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MISOPROSTOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PROTON PUMP INHIBITORS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
OMEPRAZOLE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PANTOPRAZOLE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
QUINOLONE ANTIBIOTICS					
-Overall-	5 (6.3%)	4 (5.2%)	7 (8.8%)	2 (2.5%)	18 (5.7%)
MOXIFLOXACIN HYDROCHLORIDE	(0.0%)	1 (1.3%)	3 (3.8%)	1 (1.2%)	5 (1.6%)
CIPROFLOXACIN	3 (3.8%)	(0.0%)	1 (1.3%)	(0.0%)	4 (1.3%)
CIPROFLOXACIN HYDROCHLORIDE	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
LEVOFLOXACIN	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
MOXIFLOXACIN	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
NORFLOXACIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SALICYLATES					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
ASPIRIN	(0.0%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
SEDATIVES AND HYPNOTICS					
-Overall-	4 (5.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	6 (1.9%)
ZOLPIDEM TARTRATE	2 (2.5%)	1 (1.3%)	1 (1.3%)	(0.0%)	4 (1.3%)
ESZOPICLONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ETOMIDATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS					
-Overall-	3 (3.8%)	1 (1.3%)	2 (2.5%)	(0.0%)	6 (1.9%)
FLUOXETINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
SERTRALINE HYDROCHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ESCITALOPRAM OXALATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PAROXETINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SEX HORMONES					
-Overall-	2 (2.5%)	2 (2.6%)	2 (2.5%)	5 (6.2%)	11 (3.5%)
DROSPIRENONE/ETHINYL ESTRADIOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ESTRADIOL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/ETONOGESTREL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/FERROUS FUMARATE/NORETHISTERONE ACETATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/FERROUS FUMARATE/NORETHISTERONE ACETATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ETHINYL ESTRADIOL/LEVONORGESTREL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/NORETHISTERONE ACETATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ETHINYL ESTRADIOL/NORGESTIMATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
LEVONORGESTREL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MEDROXYPROGESTERONE ACETATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROGESTERONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STATINS					
-Overall-	1 (1.3%)	1 (1.3%)	2 (2.5%)	3 (3.7%)	7 (2.2%)
ATORVASTATIN CALCIUM	1 (1.3%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	5 (1.6%)
ROSUVASTATIN	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
SIMVASTATIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STEROIDS					
-Overall-	15 (18.8%)	7 (9.1%)	8 (10.0%)	9 (11.1%)	39 (12.3%)
PREDNISONE	3 (3.8%)	2 (2.6%)	2 (2.5%)	(0.0%)	7 (2.2%)
FLUTICASONE PROPIONATE	2 (2.5%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	6 (1.9%)
DEXAMETHASONE	1 (1.3%)	1 (1.3%)	(0.0%)	3 (3.7%)	5 (1.6%)
BUDESONIDE	2 (2.5%)	(0.0%)	2 (2.5%)	(0.0%)	4 (1.3%)
MOMETASONE FUROATE	2 (2.5%)	(0.0%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
TRIAMCINOLONE ACETONIDE	2 (2.5%)	(0.0%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
METHYLPREDNISOLONE	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
METHYLPREDNISOLONE ACETATE	1 (1.3%)	1 (1.3%)	(0.0%)	1 (1.2%)	3 (0.9%)
CORTISONE ACETATE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
FLUTICASONE FUROATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
FORMOTEROL FUMARATE/MOMETASONE FUROATE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
HYDROCORTISONE	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
BETAMETHASONE DIPROPIONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CLOBETASOL PROPIONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROCORTISONE VALERATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
METHYLPREDNISOLONE ACEPONATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PREDNISOLONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRIAMCINOLONE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
SULFONAMIDES					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SULFAMETHOXAZOLE/TRIMETHOPRIM	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SULFONYLUREAS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GLICLAZIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SUPPLEMENTS					
-Overall-	2 (2.5%)	1 (1.3%)	2 (2.5%)	6 (7.4%)	11 (3.5%)
SODIUM CHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	2 (2.5%)	3 (0.9%)
LYSINE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
POTASSIUM CHLORIDE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
AMINO ACIDS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ELECTROLYTE SOLUTION NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SODIUM BICARBONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SODIUM PHOSPHATE, DIBASIC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TETRACYCLINES					
-Overall-	2 (2.5%)	1 (1.3%)	3 (3.8%)	(0.0%)	6 (1.9%)
DOXYCYCLINE	1 (1.3%)	1 (1.3%)	3 (3.8%)	(0.0%)	5 (1.6%)
MINOCYCLINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
THIAZIDE DIURETICS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
HYDROCHLOROTHIAZIDE	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
THYROID HORMONES					
-Overall-	(0.0%)	3 (3.9%)	(0.0%)	(0.0%)	3 (0.9%)
LEVOTHYROXINE SODIUM	(0.0%)	3 (3.9%)	(0.0%)	(0.0%)	3 (0.9%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.2
Concomitant Medications: New Onset During the Treatment Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
TRICYCLIC ANTIDEPRESSANTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DOXEPIN HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VACCINES, TOXOIDS AND SEROLOGIC AGENTS					
-Overall-	2 (2.5%)	4 (5.2%)	1 (1.3%)	2 (2.5%)	9 (2.8%)
INFLUENZA VIRUS VACCINE	2 (2.5%)	3 (3.9%)	1 (1.3%)	2 (2.5%)	8 (2.5%)
ACELLULAR PERTUSSIS VACCINE/DIPHTHERIA TOXOID/TETANUS TOXOID	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BOTULINUM TOXIN TYPE A	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TETANUS TOXOID	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS AND MINERALS					
-Overall-	5 (6.3%)	3 (3.9%)	2 (2.5%)	1 (1.2%)	11 (3.5%)
ASCORBIC ACID	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
MULTIVITAMINS NOS	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
VITAMIN D NOS	2 (2.5%)	1 (1.3%)	(0.0%)	(0.0%)	3 (0.9%)
CYANOCOBALAMIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VITAMIN B COMPLEX	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS AND MINERALS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the first dose of study drug (Day 1) through the end of treatment period

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
For CIU					
- Any medication use -	23 (28.8%)	32 (41.6%)	17 (21.3%)	27 (33.3%)	99 (31.1%)
ADRENERGICS/SYMPATHOMIMETICS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
EPINEPHRINE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANTIANXIETY AGENTS					
-Overall-	2 (2.5%)	3 (3.9%)	4 (5.0%)	3 (3.7%)	12 (3.8%)
HYDROXYZINE HYDROCHLORIDE	2 (2.5%)	3 (3.9%)	4 (5.0%)	3 (3.7%)	12 (3.8%)
ANTIHISTAMINES					
-Overall-	17 (21.3%)	26 (33.8%)	11 (13.8%)	22 (27.2%)	76 (23.9%)
FEXOFENADINE HYDROCHLORIDE	8 (10.0%)	8 (10.4%)	4 (5.0%)	9 (11.1%)	29 (9.1%)
CETIRIZINE HYDROCHLORIDE	5 (6.3%)	11 (14.3%)	3 (3.8%)	7 (8.6%)	26 (8.2%)
LORATADINE	1 (1.3%)	9 (11.7%)	(0.0%)	3 (3.7%)	13 (4.1%)
DESLORATADINE	2 (2.5%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	7 (2.2%)
LEVOCETIRIZINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	2 (2.5%)	1 (1.2%)	4 (1.3%)
LEVOCETIRIZINE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
RUPATADINE	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
DIMETINDENE MALEATE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
BILASTINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CETIRIZINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CLEMASTINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CYPROHEPTADINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DEXCHLORPHENIRAMINE MALEATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FEXOFENADINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHENIRAMINE MALEATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
RUPATADINE FUMARATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIMALARIAL AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HYDROXYCHLOROQUINE SULFATE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BRONCHODILATORS AND ANTIASTHMATICS					
-Overall-	4 (5.0%)	2 (2.6%)	(0.0%)	2 (2.5%)	8 (2.5%)
OMALIZUMAB	4 (5.0%)	2 (2.6%)	(0.0%)	1 (1.2%)	7 (2.2%)
SALBUTAMOL/SALBUTAMOL SULFATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DERMATOLOGIC AGENTS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CAMPHOR/DERMATOLOGIC AGENT NOS/MENTHOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	3 (3.8%)	3 (3.9%)	2 (2.5%)	3 (3.7%)	11 (3.5%)
RANITIDINE HYDROCHLORIDE	2 (2.5%)	2 (2.6%)	(0.0%)	2 (2.5%)	6 (1.9%)
RANITIDINE	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
FAMOTIDINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
IMMUNOSUPPRESSANTS					
-Overall-	(0.0%)	2 (2.6%)	1 (1.3%)	2 (2.5%)	5 (1.6%)
CICLOSPORIN	(0.0%)	1 (1.3%)	1 (1.3%)	2 (2.5%)	4 (1.3%)
MYCOPHENOLATE MOFETIL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOTRIENE RECEPTOR ANTAGONISTS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	2 (2.5%)	4 (1.3%)
MONTELUKAST SODIUM	1 (1.3%)	1 (1.3%)	(0.0%)	2 (2.5%)	4 (1.3%)
LINCOMYCIN ANTIBIOTICS					

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CLINDAMYCIN PHOSPHATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STEROID/OTHER DRUG COMBINATIONS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BETAMETHASONE/DEXCHLORPHENIRAMINE MALEATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
STEROIDS					
-Overall-	7 (8.8%)	12 (15.6%)	8 (10.0%)	15 (18.5%)	42 (13.2%)
PREDNISONE	6 (7.5%)	9 (11.7%)	3 (3.8%)	12 (14.8%)	30 (9.4%)
METHYLPREDNISOLONE	(0.0%)	(0.0%)	1 (1.3%)	4 (4.9%)	5 (1.6%)
BETAMETHASONE	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
DEXAMETHASONE	(0.0%)	(0.0%)	2 (2.5%)	1 (1.2%)	3 (0.9%)
METHYLPREDNISOLONE ACETATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
PREDNISOLONE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
CLOBETASOL PROPIONATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METHYLPREDNISOLONE SODIUM SUCCINATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PREDNISOLONE HEMISUCCINATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRIAMCINOLONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TRIAMCINOLONE ACETONIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TRICYCLIC ANTIDEPRESSANTS					
-Overall-	(0.0%)	3 (3.9%)	2 (2.5%)	(0.0%)	5 (1.6%)
DOXEPIN HYDROCHLORIDE	(0.0%)	3 (3.9%)	2 (2.5%)	(0.0%)	5 (1.6%)
VACCINES, TOXOIDS AND SEROLOGIC AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGENIC EXTRACTS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
Not for CIU					
- Any medication use -	31 (38.8%)	30 (39.0%)	31 (38.8%)	25 (30.9%)	117 (36.8%)
5-HT1 AGONISTS					
-Overall-	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)	2 (0.6%)
RIZATRIPTAN BENZOATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SUMATRIPTAN SUCCINATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
5-HT3 ANTAGONISTS					
-Overall-	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ONDANSETRON HYDROCHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ADRENERGICS/SYMPATHOMIMETICS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	4 (4.9%)	5 (1.6%)
EPINEPHRINE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
OXYMETAZOLINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PHENYLEPHRINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
XYLOMETAZOLINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ALPHA-ADRENORECEPTOR ANTAGONISTS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
TAMSULOSIN HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
AMINOSALICYLATES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SULFASALAZINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANALGESIC/OTHER DRUG COMBINATIONS					
-Overall-	3 (3.8%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	7 (2.2%)
HYDROCODONE TARTRATE/PARACETAMOL	2 (2.5%)	2 (2.6%)	(0.0%)	1 (1.2%)	5 (1.6%)
ASPIRIN/CAFFEINE/PARACETAMOL	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANALGESICS					
-Overall-	5 (6.3%)	3 (3.9%)	5 (6.3%)	3 (3.7%)	16 (5.0%)
PARACETAMOL	4 (5.0%)	2 (2.6%)	3 (3.8%)	1 (1.2%)	10 (3.1%)
OXYCODONE HYDROCHLORIDE/PARACETAMOL	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
PHENAZOPYRIDINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	1 (1.2%)	2 (0.6%)
CODEINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CODEINE PHOSPHATE/PARACETAMOL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FENTANYL CITRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROMORPHONE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OXYCODONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
TRAMADOL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANGIOTENSIN II RECEPTOR ANTAGONISTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	2 (2.5%)	3 (0.9%)
LOSARTAN POTASSIUM	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OLMESARTAN MEDOXOMIL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VALSARTAN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
LISINOPRIL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RAMIPRIL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANOREXIANTS AND CNS STIMULANTS					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
AMPHETAMINE ASPARTATE/AMPHETAMINE SULFATE/DEXTROAMPHETAMINE SACCHARATE/DEXT	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTACIDS NEC					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MAGNESIUM OXIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ANTIANDROGENS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DUTASTERIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIANEMIC AGENTS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
FERROUS GLYCINE SULFATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FERROUS SULFATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
IRON DEXTRAN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANTIANXIETY AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYDROXYZINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTICOAGULANTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ENOXAPARIN SODIUM	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTICONVULSANTS NEC					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
TOPIRAMATE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
GABAPENTIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIDEPRESSANTS NEC					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VENLAFAXINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIEMETICS NEC					
-Overall-	3 (3.8%)	1 (1.3%)	1 (1.3%)	(0.0%)	5 (1.6%)
MECLIZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
METOCLOPRAMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
METOCLOPRAMIDE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIFUNGAL AGENTS					
-Overall-	5 (6.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	7 (2.2%)
FLUCONAZOLE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
TERBINAFINE HYDROCHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
AMPHOTERICIN B	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CICLOPIROX OLAMINE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
NYSTATIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIGOUT AGENTS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ALLOPURINOL	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIHISTAMINES					
-Overall-	3 (3.8%)	(0.0%)	1 (1.3%)	3 (3.7%)	7 (2.2%)
AZELASTINE HYDROCHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
CETIRIZINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CLEMASTINE FUMARATE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DIPHENHYDRAMINE NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
KETOTIFEN FUMARATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIHYPERTENSIVE AGENTS NEC					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
HYDROCHLOROTHIAZIDE/LOSARTAN POTASSIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIMIGRAINE AGENTS NEC					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
DICHLORALPHENAZONE/ISOMETHEPTENE MUCATE/PARACETAMOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
NAPROXEN SODIUM/SUMATRIPTAN SUCCINATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ANTIPSYCHOTIC AND ANTIMANIC AGENTS					
-Overall-	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
DROPERIDOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FLUPENTIXOL/MELITRACEN HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANTISPASMODICS AND ANTICHOLINERGICS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
HOMATROPINE NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SCOPOLAMINE NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ANTIVIRAL AGENTS NEC					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ACICLOVIR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VALACICLOVIR HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
BENZODIAZEPINES					
-Overall-	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
ALPRAZOLAM	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LORAZEPAM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MIDAZOLAM NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BETA-ADRENOCEPTOR BLOCKING AGENTS					
-Overall-	1 (1.3%)	1 (1.3%)	2 (2.5%)	(0.0%)	4 (1.3%)
METOPROLOL NOS	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ATENOLOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SOTALOL HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BIGUANIDES					

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Overall-	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
METFORMIN HYDROCHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
BRONCHODILATORS AND ANTIASTHMATICS					
-Overall-	3 (3.8%)	3 (3.9%)	2 (2.5%)	3 (3.7%)	11 (3.5%)
SALBUTAMOL/SALBUTAMOL SULFATE	2 (2.5%)	2 (2.6%)	1 (1.3%)	3 (3.7%)	8 (2.5%)
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
IPRATROPIUM BROMIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LEVOSALBUTAMOL HYDROCHLORIDE/LEVOSALBUTAMOL TARTRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OMALIZUMAB	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TIOTROPIUM BROMIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CALCIUM CHANNEL BLOCKING AGENTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LERCANIDIPINE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CEPHALOSPORIN ANTIBIOTICS					
-Overall-	1 (1.3%)	3 (3.9%)	3 (3.8%)	1 (1.2%)	8 (2.5%)
CEPHALEXIN	(0.0%)	1 (1.3%)	2 (2.5%)	(0.0%)	3 (0.9%)
CEFDINIR	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
CEFAZOLIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CEFTRIAXONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CEFUROXIME	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
COLD AND SINUS REMEDIES					
-Overall-	3 (3.8%)	7 (9.1%)	4 (5.0%)	4 (4.9%)	18 (5.7%)
DEXTROMETHORPHAN HYDROBROMIDE/DOXYLAMINE SUCCINATE/PARACETAMOL	1 (1.3%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	6 (1.9%)
COLD AND SINUS REMEDIES	(0.0%)	2 (2.6%)	2 (2.5%)	(0.0%)	4 (1.3%)
GUAIFENESIN/PSEUDOEPHEDRINE HYDROCHLORIDE	(0.0%)	2 (2.6%)	(0.0%)	1 (1.2%)	3 (0.9%)
COLD AND SINUS REMEDIES/PARACETAMOL	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
ASCORBIC ACID/CAFFEINE/CHLORPHENIRAMINE MALEATE/PARACETAMOL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CHLORPHENIRAMINE POLISTIREX/HYDROCODONE POLISTIREX	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
CODEINE/COLD AND SINUS REMEDIES	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DIPHENHYDRAMINE CITRATE/IBUPROFEN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DOXYLAMINE SUCCINATE/PARACETAMOL/PHENYLEPHRINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
COUGH PREPARATIONS					
-Overall-	(0.0%)	5 (6.5%)	2 (2.5%)	2 (2.5%)	9 (2.8%)
DEXTROMETHORPHAN HYDROBROMIDE/GUAIFENESIN	(0.0%)	2 (2.6%)	(0.0%)	1 (1.2%)	3 (0.9%)
GUAIFENESIN	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANTITUSSIVE NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
BENZONATATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CODEINE PHOSPHATE/PROMETHAZINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
DEXTROMETHORPHAN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
COX-2 INHIBITORS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
CELECOXIB	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
FOLIC ACID AND DERIVATIVES					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
FOLIC ACID	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS					
-Overall-	4 (5.0%)	(0.0%)	1 (1.3%)	(0.0%)	5 (1.6%)
ALOE/BLACK WALNUT/CASCARA SAGRADA/GRAPE/RHUBARB/RUMEX CRISPUS/SENNA/SLIPPER	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DOCOSAHEXAENOIC ACID/EICOSAPENTAENOIC ACID	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FISH OIL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

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Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
HERBAL,HOMEOPATHIC,& DIETARY SUPPLEMENTS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LACTOBACILLUS ACIDOPHILUS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UBIDECARENONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HISTAMINE H2-RECEPTOR ANTAGONISTS					
-Overall-	1 (1.3%)	2 (2.6%)	1 (1.3%)	3 (3.7%)	7 (2.2%)
RANITIDINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
FAMOTIDINE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
RANITIDINE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
IMMUNOMODULATORS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INTERFERON BETA-1A	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INSULINS					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
INSULIN (SUSPENSION), ISOPHANE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INSULIN HUMAN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
LINCOMYCIN ANTIBIOTICS					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
CLINDAMYCIN	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
LOCAL ANESTHETICS					
-Overall-	2 (2.5%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	6 (1.9%)
BUPIVACAINE HYDROCHLORIDE	2 (2.5%)	(0.0%)	1 (1.3%)	(0.0%)	3 (0.9%)
EPINEPHRINE/LIDOCAINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LIDOCAINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LIDOCAINE HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ROPIVACAINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
MACROLIDE ANTIBIOTICS					
-Overall-	3 (3.8%)	3 (3.9%)	3 (3.8%)	3 (3.7%)	12 (3.8%)
AZITHROMYCIN	2 (2.5%)	2 (2.6%)	3 (3.8%)	3 (3.7%)	10 (3.1%)
CLARITHROMYCIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ERYTHROMYCIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
MISCELLANEOUS ANTIMICROBIALS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	(0.0%)	2 (0.6%)
ANTIBIOTICS NOS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TRIMETHOPRIM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MUSCLE RELAXANTS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NITROFURANS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
NITROFURANTOIN	1 (1.3%)	(0.0%)	1 (1.3%)	1 (1.2%)	3 (0.9%)
NON-STEROIDAL ANTI-INFLAMMATORIES					
-Overall-	2 (2.5%)	6 (7.8%)	2 (2.5%)	2 (2.5%)	12 (3.8%)
IBUPROFEN	1 (1.3%)	4 (5.2%)	1 (1.3%)	1 (1.2%)	7 (2.2%)
KETOROLAC TROMETAMOL	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
DICLOFENAC	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
DIPYRONE SODIUM SALT	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NAPROXEN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
OPIOID ANALGESICS					
-Overall-	2 (2.5%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	7 (2.2%)
HYDROCODONE NOS	1 (1.3%)	1 (1.3%)	2 (2.5%)	(0.0%)	4 (1.3%)
MORPHINE SULFATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
TAPENTADOL HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PENICILLINS					
-Overall-	4 (5.0%)	3 (3.9%)	6 (7.5%)	1 (1.2%)	14 (4.4%)
AMOXICILLIN	3 (3.8%)	1 (1.3%)	2 (2.5%)	1 (1.2%)	7 (2.2%)
AMOXICILLIN/CLAVULANATE POTASSIUM	1 (1.3%)	2 (2.6%)	2 (2.5%)	(0.0%)	5 (1.6%)
DICLOXACILLIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PENICILLIN NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PENICILLIN V POTASSIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PHARMACEUTIC AIDS					
-Overall-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SODIUM HYALURONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PHARMACOTHERAPEUTIC CLASS(ES) NOT KNOWN					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
GENERIC COMPONENT(S) NOT KNOWN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
PROTON PUMP INHIBITORS					
-Overall-	1 (1.3%)	(0.0%)	1 (1.3%)	3 (3.7%)	5 (1.6%)
OMEPRAZOLE	(0.0%)	(0.0%)	(0.0%)	3 (3.7%)	3 (0.9%)
ESOMEPRAZOLE MAGNESIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
OMEPRAZOLE/SODIUM BICARBONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
QUINOLONE ANTIBIOTICS					
-Overall-	2 (2.5%)	1 (1.3%)	5 (6.3%)	2 (2.5%)	10 (3.1%)
LEVOFLOXACIN	1 (1.3%)	1 (1.3%)	2 (2.5%)	2 (2.5%)	6 (1.9%)
CIPROFLOXACIN	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
CIPROFLOXACIN HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MOXIFLOXACIN HYDROCHLORIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
SALICYLATES					
-Overall-	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ASPIRIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SEDATIVES AND HYPNOTICS					
-Overall-	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
ESZOPICLONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
ZOLPIDEM TARTRATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ZOPICLONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS					
-Overall-	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
DULOXETINE HYDROCHLORIDE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FLUOXETINE HYDROCHLORIDE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SEX HORMONES					
-Overall-	2 (2.5%)	1 (1.3%)	2 (2.5%)	(0.0%)	5 (1.6%)
ESTRADIOL	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/LEVONORGESTREL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ETHINYL ESTRADIOL/NORGESTIMATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
LEVONORGESTREL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NORETHISTERONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
SMOKING CESSATION THERAPIES					
-Overall-	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VARENICLINE TARTRATE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
STATINS					
-Overall-	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ATORVASTATIN CALCIUM	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
ROSUVASTATIN	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
STEROIDS					
-Overall-	9 (11.3%)	4 (5.2%)	6 (7.5%)	6 (7.4%)	25 (7.9%)
PREDNISONE	5 (6.3%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	10 (3.1%)
DEXAMETHASONE	2 (2.5%)	(0.0%)	1 (1.3%)	3 (3.7%)	6 (1.9%)
FLUTICASONE PROPIONATE	1 (1.3%)	1 (1.3%)	1 (1.3%)	(0.0%)	3 (0.9%)
BECLOMETASONE DIPROPIONATE	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)	2 (0.6%)
BUDESONIDE	1 (1.3%)	1 (1.3%)	(0.0%)	(0.0%)	2 (0.6%)
MOMETASONE FUROATE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PREDNISOLONE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BETAMETHASONE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
CLOBETASOL PROPIONATE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DESOXIMETASONE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
METHYLPREDNISOLONE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TRIAMCINOLONE ACETONIDE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SULFONAMIDES					
-Overall-	(0.0%)	2 (2.6%)	2 (2.5%)	1 (1.2%)	5 (1.6%)
SULFAMETHOXAZOLE/TRIMETHOPRIM	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	4 (1.3%)
SULFAMETHOXAZOLE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SUPPLEMENTS					
-Overall-	2 (2.5%)	2 (2.6%)	1 (1.3%)	1 (1.2%)	6 (1.9%)
SODIUM CHLORIDE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
DEXTROSE/RINGER'S INJECTION, LACTATED	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
INTRAVENOUS SOLUTION NOS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LYSINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
SODIUM BICARBONATE	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
TETRACYCLINES					
-Overall-	(0.0%)	(0.0%)	2 (2.5%)	(0.0%)	2 (0.6%)
DOXYCYCLINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class. Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.1/9.3
Concomitant Medications: New Onset During the Follow-up Period
Modified Intention to Treat Patients

Medication Class Generic Name	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)	All Patients (n=318)
MINOCYCLINE	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
THIAZIDE DIURETICS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
HYDROCHLOROTHIAZIDE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
THYROID HORMONES					
-Overall-	(0.0%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
LEVOTHYROXINE SODIUM	(0.0%)	3 (3.9%)	1 (1.3%)	1 (1.2%)	5 (1.6%)
TRICYCLIC ANTIDEPRESSANTS					
-Overall-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DOXEPIN HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OPIPRAMOL HYDROCHLORIDE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VACCINES, TOXOIDS AND SEROLOGIC AGENTS					
-Overall-	(0.0%)	2 (2.6%)	3 (3.8%)	1 (1.2%)	6 (1.9%)
INFLUENZA VIRUS VACCINE	(0.0%)	1 (1.3%)	1 (1.3%)	(0.0%)	2 (0.6%)
ALLERGENIC EXTRACTS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
BOTULINUM TOXIN TYPE A	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
PNEUMOCOCCAL VACCINE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TETANUS TOXOID	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)
VITAMINS AND MINERALS					
-Overall-	2 (2.5%)	1 (1.3%)	3 (3.8%)	(0.0%)	6 (1.9%)
MINERALS NOS/MULTIVITAMINS NOS	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
CYANOCOBALAMIN	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
MULTIVITAMINS NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VITAMIN D NOS	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)	1 (0.3%)
VITAMINS NOS	(0.0%)	1 (1.3%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple uses of a specific medication for a patient were counted once in the frequency for the medication. Similarly, multiple uses within a specific medication class for a patient were counted once in the frequency for the medication class.
Includes concomitant medications with a start date any time after the end of treatment period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_med)
Database (CLOSED) Datasets (pat meds)
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Table 14.2/2.1
Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Itch Severity Score				
n	80	77	80	81
Mean (SD)	-3.63 (5.22)	-6.46 (6.14)	-6.66 (6.28)	-9.40 (5.73)
SE	0.58	0.70	0.70	0.64
Median	-2.3	-6.0	-6.0	-10.0
Range	-18.5 - 7.5	-21.0 - 4.0	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-4.80, -2.47)	(-7.85, -5.06)	(-8.05, -5.26)	(-10.66, -8.13)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.96	-2.95	-5.80
95% CI of the LS Means Difference		(-4.71, -1.21)	(-4.72, -1.18)	(-7.49, -4.10)
p-value^		0.0010	0.0012	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/4.1
Change from Baseline in UAS7 at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in UAS7				
n	80	77	80	81
Mean (SD)	-8.01 (11.47)	-13.82 (13.26)	-14.44 (12.95)	-20.75 (12.17)
SE	1.28	1.51	1.45	1.35
Median	-4.0	-13.0	-14.8	-22.0
Range	-39.0 - 14.5	-42.0 - 7.0	-40.0 - 4.5	-40.0 - 1.0
95% CI of the Mean	(-10.56, -5.45)	(-16.83, -10.81)	(-17.32, -11.55)	(-23.44, -18.06)
Treatment Difference in LS Means* (relative to the Placebo group)		-5.75	-6.54	-12.80
95% CI of the LS Means Difference		(-9.59, -1.92)	(-10.33, -2.75)	(-16.44, -9.16)
p-value^		0.0035	0.0008	<.0001

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline UAS7 (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/6.1
Change from Baseline in Weekly Number of Hives Score at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Number of Hives Score				
n	80	77	80	81
Mean (SD)	-4.37 (6.60)	-7.36 (7.52)	-7.78 (7.08)	-11.35 (7.25)
SE	0.74	0.86	0.79	0.81
Median	-1.8	-5.8	-7.3	-11.8
Range	-21.0 - 7.3	-21.0 - 5.5	-21.0 - 2.1	-21.0 - 3.0
95% CI of the Mean	(-5.84, -2.90)	(-9.07, -5.66)	(-9.36, -6.20)	(-12.96, -9.75)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.75	-3.44	-6.93
95% CI of the LS Means Difference		(-4.95, -0.54)	(-5.57, -1.32)	(-9.10, -4.76)
p-value^		0.0149	0.0017	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly number of hives score (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hive_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
: Generated 25JAN13 14:11 Page 1 of 1

Table 14.2/8
Time (Weeks) to Minimally Important Difference (MID) Response in Weekly Itch Severity Score up to Week 12
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of patients	80	77	80	81
Number of patients with an event (%)	57 (71.3%)	57 (74.0%)	66 (82.5%)	76 (93.8%)
Number of patients without an event (%)	23 (28.8%)	20 (26.0%)	14 (17.5%)	5 (6.2%)
Time to MID response (weeks)				
Median	4.0	3.0	2.0	1.0
(95% CI)	(2.0, 6.0)	(2.0, 5.0)	(2.0, 3.0)	(1.0, 2.0)
25th - 75th percentile	2.0 - 11.0	1.0 - 9.0	1.0 - 7.0	1.0 - 3.0
Minimum - Maximum	1.0 - 12.0+	0.0+ - 12.0+	1.0 - 12.0+	0.0+ - 12.0+
Stratified analysis				
Hazard ratio (relative to the Placebo group)		1.39	1.49	2.34
(95% CI)		(0.95 , 2.03)	(1.04 , 2.14)	(1.63 , 3.36)
p-value		0.0879	0.0301	<.0001

+ = censored value.
Summaries of time to event variable (median, percentiles, and range) are based on Kaplan-Meier estimates of the distribution of the time to a reduction from baseline in weekly itch severity score of >=5 points (MID response) by week 12. The 95% confidence interval (CI) for the median was computed using the method of Brookmeyer and Crowley. Hazard ratios are estimated using Cox proportional hazards (PH) models stratified by baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg). Separate models were run for each omalizumab dose compared to placebo.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_mid_tte)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 14:26 Page 1 of 1

Table 14.2/9
Patients with UAS7 <= 6 at Week 12
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 12 UAS7				
<=6	9 (11.3%)	20 (26.0%)	32 (40.0%)	42 (51.9%)
>6	71 (88.8%)	57 (74.0%)	48 (60.0%)	39 (48.1%)
p-value* (relative to the Placebo group)		0.0148	<.0001	<.0001

* p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 12, the patient will be counted as Week 12 UAS7 > 6.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_wk12)
Database (CLOSED) Datasets (pat pateff diaryeff)
: Generated 25JAN13 14:45 Page 1 of 1

Table 14.2/10
Patients with Weekly Itch Severity Score Minimally Important Difference (MID) Response at Week 12
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Itch Severity Score at Week 12				
<=-5	29 (36.3%)	43 (55.8%)	45 (56.3%)	61 (75.3%)
>-5	51 (63.8%)	34 (44.2%)	35 (43.8%)	20 (24.7%)
p-value* (relative to the Placebo group)		0.0118	0.0226	<.0001

* p-value is derived from the Cochran Mantel Haenszel test stratified by baseline weekly itch severity score (<13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 12, the patient will be counted as change from baseline > - 5.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_mid)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 14:24 Page 1 of 1

Table 14.2/11.1
Change from Baseline in Weekly Size of Largest Hive Score at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Size of Largest Hive Score				
n	80	77	80	81
Mean (SD)	-3.93 (5.44)	-6.20 (6.29)	-6.96 (6.68)	-9.79 (6.66)
SE	0.61	0.72	0.75	0.74
Median	-2.8	-4.5	-6.0	-10.5
Range	-21.0 - 4.0	-21.0 - 2.0	-21.0 - 2.5	-21.0 - 3.0
95% CI of the Mean	(-5.15, -2.72)	(-7.63, -4.78)	(-8.45, -5.48)	(-11.26, -8.32)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.34	-3.16	-5.73
95% CI of the LS Means Difference		(-4.17, -0.51)	(-5.05, -1.27)	(-7.59, -3.87)
p-value^		0.0124	0.0012	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly size of largest hive score (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lghive_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
: Generated 25JAN13 14:28 Page 1 of 1

Table 14.2/13
Change from Baseline in Overall Dermatology Life Quality Index (DLQI) Score at Week 12 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Overall Dermatology Life Quality Index (DLQI) Score at Week 12				
n	62	66	63	72
Mean (SD)	-6.13 (6.25)	-6.33 (6.08)	-8.00 (7.24)	-10.29 (7.23)
SE	0.79	0.75	0.91	0.85
Median	-5.0	-5.0	-8.0	-10.5
Range	-24.0 - 9.0	-24.0 - 8.0	-30.0 - 9.0	-26.0 - 5.0
95% CI of the Mean	(-7.72, -4.54)	(-7.83, -4.84)	(-9.82, -6.18)	(-11.99, -8.59)
Treatment Difference in LS Means* (relative to the Placebo group)		0.26	-1.31	-4.08
95% CI of the LS Means Difference		(-1.76, 2.28)	(-3.46, 0.84)	(-5.96, -2.20)
p-value^		0.7956	0.2286	<.0001

Baseline overall DLQI score is the measurement taken prior to dosing on Day 1.
Observed data only. Patients who discontinued before Week 12 will have their Week 12 score missing. No imputation for missing Week 12 scores.
*The LS mean was estimated using ANCOVA model. The strata are for baseline overall DLQI score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_wk12)
Database (CLOSED) Datasets (pat dlqieff)
: Generated 25JAN13 14:01 Page 1 of 1

Table 14.2/16.1
Proportion of Angioedema-Free Days from Week 4 to Week 12 of Therapy
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Proportion of Angioedema-Free Days from Week 4 to Week 12				
n	66	69	70	74
Mean (SD)	88.2% (19.4%)	86.5% (28.4%)	89.6% (20.6%)	96.1% (11.3%)
SE	2.4%	3.4%	2.5%	1.3%
Median	98.1%	100.0%	100.0%	100.0%
Range	2.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	23.2% - 100.0%
95% CI of the Mean	(83.5%, 93.0%)	(79.7%, 93.4%)	(84.7%, 94.5%)	(93.5%, 98.7%)
p-value^		0.4867	0.1747	<.0001

The proportion of angioedema-free days from Week 4 to Week 12 is defined as the number of days for which the patient indicated a `No` response to the angioedema question in the daily diary divided by the total number of days with a non-missing diary entry starting on the Week 4 visit date and ending the day prior to the Week 12 visit date. Patients who withdrew before the Week 4 visit or who have missing responses for > 40% of the daily diary entries between the Week 4 study visit and the Week 12 study visit will not be included in this analysis.
^ p-value is derived from stratified Wilcoxon test. Stratification variables are presence of angioedema at baseline (Yes vs. No) and baseline weight (< 80 kg vs. >= 80 kg).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_angio_pval)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 13:54 Page 1 of 1

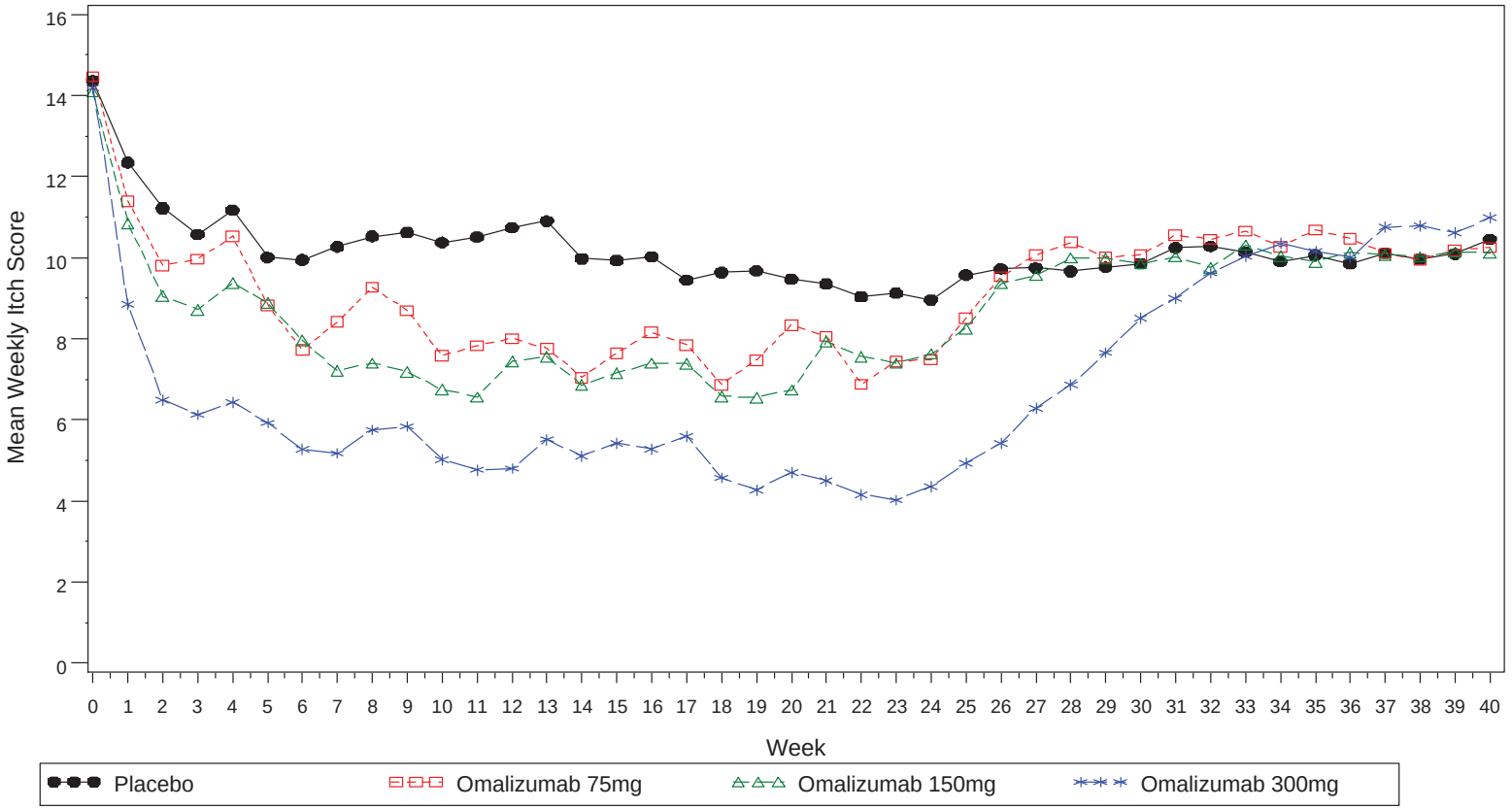
Table 14.2/52
Patients with Complete Response (UAS7=0) at Week 12
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Complete Response (UAS7=0)				
Yes	7 (8.8%)	9 (11.7%)	12 (15.0%)	29 (35.8%)
No	73 (91.3%)	68 (88.3%)	68 (85.0%)	52 (64.2%)
p-value* (relative to the Placebo group)		0.4580	0.2087	<.0001

* p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 12, the patient will be counted as non-responder.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_zero_wk12)
Database (CLOSED) Datasets (pat pateff diaryeff)
: Generated 25JAN13 14:48 Page 1 of 1

Figure 14.2/1.4
Mean Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using baseline weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_mean)
Database (CLOSED) Datasets (diaryeff)
: Generated 25JAN13 14:58 Page 1 of 1

Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 1																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	12.34	3.96	12.5	4.0	21.0	-2.02	3.22	0.36	-2.0	-11.5	6.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	11.40	4.30	11.5	3.5	21.0	-3.07	4.07	0.46	-3.0	-12.0	5.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.85	4.91	10.3	0.5	21.0	-3.24	4.22	0.47	-2.7	-14.0	4.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	8.86	4.32	9.0	1.0	18.0	-5.34	4.44	0.49	-5.0	-17.0	5.5
Week 2																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	11.22	5.14	12.0	0.0	20.0	-3.15	4.70	0.53	-2.0	-15.5	5.1
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	9.80	5.90	9.5	0.0	21.0	-4.67	5.73	0.65	-4.0	-19.0	5.8
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.05	5.77	8.0	0.0	21.0	-5.04	5.57	0.62	-5.0	-18.5	5.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	6.49	5.47	6.5	0.0	21.0	-7.71	5.57	0.62	-7.0	-21.0	1.0
Week 3																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.58	4.90	11.3	0.0	20.5	-3.79	4.60	0.51	-3.0	-15.5	8.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	9.97	5.34	10.0	0.0	21.0	-4.50	4.89	0.56	-4.0	-17.5	7.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	8.72	5.95	8.0	0.0	21.0	-5.38	5.68	0.64	-5.0	-18.0	6.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	6.14	5.84	5.0	0.0	21.0	-8.06	5.96	0.66	-7.5	-21.0	3.5
Week 4																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	11.17	5.20	12.0	0.0	21.0	-3.19	4.48	0.50	-2.0	-15.5	5.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.53	5.56	10.0	0.0	21.0	-3.94	5.09	0.58	-2.5	-15.5	6.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.38	5.97	9.5	0.0	21.0	-4.71	5.44	0.61	-4.5	-21.0	5.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	6.43	5.95	6.5	0.0	21.0	-7.77	5.89	0.65	-7.5	-19.0	5.5
Week 5																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.01	5.29	10.5	0.0	20.0	-4.36	5.10	0.57	-3.0	-17.5	5.1
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.83	5.88	8.5	0.0	21.0	-5.64	5.89	0.67	-4.4	-20.5	5.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	8.88	6.23	9.0	0.0	21.0	-5.21	6.02	0.67	-4.0	-21.0	6.1
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.93	5.97	5.5	0.0	21.0	-8.27	5.93	0.66	-8.2	-19.0	4.5
Week 6																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.94	5.72	10.3	0.0	20.0	-4.43	5.34	0.60	-3.3	-19.0	4.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.73	5.87	7.0	0.0	21.0	-6.74	6.04	0.69	-7.0	-20.5	5.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.96	6.24	7.0	0.0	21.0	-6.13	6.15	0.69	-5.3	-21.0	6.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.28	5.69	4.0	0.0	21.0	-8.92	5.57	0.62	-9.0	-21.0	2.5

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
: Generated 25JAN13 14:30 Page 1 of 7

Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 7																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.27	5.43	10.5	0.0	20.0	-4.10	5.10	0.57	-2.5	-17.5	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.42	6.43	8.0	0.0	21.0	-6.05	5.99	0.68	-6.0	-20.5	5.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.21	6.31	6.5	0.0	21.0	-6.89	6.28	0.70	-7.0	-21.0	6.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.18	5.71	2.5	0.0	21.0	-9.01	5.92	0.66	-9.0	-21.0	2.5
Week 8																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.52	5.49	11.0	0.0	20.0	-3.85	5.09	0.57	-2.0	-19.0	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	9.28	6.57	9.0	0.0	21.0	-5.19	6.03	0.69	-4.5	-21.0	6.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.40	6.57	7.0	0.0	21.0	-6.69	6.52	0.73	-6.3	-21.0	11.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.75	6.16	4.0	0.0	21.0	-8.45	6.16	0.68	-8.5	-21.0	5.5
Week 9																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.62	6.00	12.0	0.0	20.5	-3.75	5.37	0.60	-1.5	-19.0	6.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.70	6.03	8.5	0.0	21.0	-5.77	6.10	0.70	-4.5	-21.0	5.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.19	6.19	6.3	0.0	21.0	-6.90	6.26	0.70	-6.8	-21.0	2.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.84	6.03	4.0	0.0	21.0	-8.35	6.00	0.67	-8.5	-21.0	4.5
Week 10																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.37	5.71	10.8	0.0	20.5	-4.00	5.30	0.59	-3.5	-18.0	8.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.58	6.00	7.0	0.0	21.0	-6.89	6.37	0.73	-7.0	-21.0	6.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.75	6.14	5.0	0.0	21.0	-7.34	6.23	0.70	-7.8	-21.0	5.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.02	5.66	3.0	0.0	21.0	-9.17	5.98	0.66	-10.0	-21.0	4.0
Week 11																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.51	5.84	10.8	0.0	21.0	-3.86	5.05	0.56	-2.4	-18.5	5.8
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.83	5.81	7.5	0.0	21.0	-6.64	6.09	0.69	-6.5	-21.0	4.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.57	6.25	5.4	0.0	21.0	-7.53	6.38	0.71	-8.0	-21.0	4.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.77	5.45	2.5	0.0	21.0	-9.43	5.82	0.65	-10.5	-21.0	2.5
Week 12																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.73	5.99	11.5	0.0	20.5	-3.63	5.22	0.58	-2.3	-18.5	7.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.01	5.92	7.6	0.0	21.0	-6.46	6.14	0.70	-6.0	-21.0	4.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.44	6.59	6.8	0.0	21.0	-6.66	6.28	0.70	-6.0	-21.0	5.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.80	5.55	2.5	0.0	21.0	-9.40	5.73	0.64	-10.0	-19.5	0.0

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
: Generated 25JAN13 14:30 Page 2 of 7

Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 13																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.91	5.79	11.3	0.0	20.5	-3.46	5.31	0.59	-1.3	-19.0	6.6
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.77	5.96	7.0	0.0	21.0	-6.70	6.23	0.71	-6.0	-21.0	2.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.55	6.11	7.8	0.0	21.0	-6.54	6.32	0.71	-6.0	-21.0	2.3
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.52	6.06	2.5	0.0	21.0	-8.68	6.42	0.71	-9.0	-20.5	2.3
Week 14																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.98	6.02	10.0	0.0	21.0	-4.39	5.60	0.63	-3.0	-19.0	8.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.05	6.45	7.0	0.0	21.0	-7.42	6.62	0.75	-8.0	-21.0	6.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.86	6.03	6.5	0.0	21.0	-7.24	5.94	0.66	-6.7	-19.0	0.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.10	6.10	2.0	0.0	21.0	-9.09	6.24	0.69	-10.0	-19.0	6.5
Week 15																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.93	5.86	10.0	0.0	20.5	-4.44	5.40	0.60	-2.5	-18.5	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.65	6.75	7.0	0.0	21.0	-6.81	6.94	0.79	-7.0	-21.0	7.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.16	6.19	7.3	0.0	21.0	-6.93	6.19	0.69	-6.5	-19.5	3.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.42	6.36	2.0	0.0	21.0	-8.78	6.55	0.73	-9.5	-19.5	7.5
Week 16																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.03	6.03	10.5	0.0	20.5	-4.34	5.65	0.63	-2.5	-19.0	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.16	6.95	7.5	0.0	21.0	-6.31	7.04	0.80	-6.0	-21.0	10.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.40	6.39	7.0	0.0	21.0	-6.69	6.04	0.68	-5.5	-21.0	1.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.28	6.21	2.0	0.0	21.0	-8.92	6.21	0.69	-9.5	-19.5	2.0
Week 17																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.44	6.22	9.8	0.0	20.5	-4.92	5.76	0.64	-3.3	-18.5	4.8
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.86	6.97	8.0	0.0	21.0	-6.61	7.04	0.80	-6.0	-21.0	11.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.38	6.55	6.8	0.0	21.0	-6.71	6.58	0.74	-6.5	-21.0	4.1
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.59	6.43	3.0	0.0	21.0	-8.60	6.19	0.69	-9.0	-19.5	0.0
Week 18																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.64	6.06	9.3	0.0	20.5	-4.73	5.52	0.62	-4.0	-19.0	6.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	6.86	6.89	5.5	0.0	21.0	-7.60	7.21	0.82	-9.0	-21.0	11.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.58	6.17	6.8	0.0	21.0	-7.51	6.29	0.70	-8.0	-21.0	0.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.57	5.76	2.0	0.0	21.0	-9.62	5.91	0.66	-10.5	-19.5	1.5

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 19																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.67	6.31	9.4	0.0	21.0	-4.70	5.68	0.64	-3.8	-16.5	9.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.48	6.67	7.0	0.0	21.0	-6.99	6.95	0.79	-7.5	-21.0	9.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.55	6.08	6.2	0.0	21.0	-7.54	6.27	0.70	-7.5	-21.0	1.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.27	5.74	1.0	0.0	21.0	-9.92	5.70	0.63	-11.0	-19.5	0.0
Week 20																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.47	6.39	8.5	0.0	21.0	-4.90	5.73	0.64	-3.3	-18.0	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.34	6.79	7.5	0.0	21.0	-6.13	6.70	0.76	-6.1	-21.0	8.8
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	6.74	6.12	5.7	0.0	21.0	-7.35	6.20	0.69	-7.5	-21.0	3.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.70	6.10	1.0	0.0	21.0	-9.50	5.96	0.66	-10.5	-19.5	0.0
Week 21																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.35	6.48	10.0	0.0	20.5	-5.02	5.87	0.66	-3.0	-18.7	2.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.07	6.39	8.8	0.0	21.0	-6.40	6.67	0.76	-6.0	-21.0	8.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.94	6.21	8.1	0.0	21.0	-6.16	6.35	0.71	-4.9	-21.0	3.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.50	6.02	1.0	0.0	21.0	-9.70	6.22	0.69	-11.0	-19.5	1.5
Week 22																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.03	6.63	7.5	0.0	20.5	-5.33	5.94	0.66	-3.5	-16.5	9.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	6.88	6.19	6.5	0.0	21.0	-7.58	6.71	0.76	-9.5	-21.0	9.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.56	6.43	7.6	0.0	21.0	-6.54	6.72	0.75	-5.3	-21.0	3.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.15	6.07	0.0	0.0	21.0	-10.05	5.96	0.66	-11.0	-19.5	0.0
Week 23																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.12	6.52	7.5	0.0	20.5	-5.25	5.90	0.66	-4.2	-17.5	8.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.44	6.51	7.0	0.0	21.0	-7.03	6.85	0.78	-8.5	-21.0	8.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.40	6.23	6.8	0.0	21.0	-6.69	6.51	0.73	-6.1	-21.0	3.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.03	6.10	0.0	0.0	21.0	-10.17	5.90	0.66	-10.5	-19.5	2.1
Week 24																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	8.96	6.50	8.8	0.0	20.5	-5.41	5.76	0.64	-4.5	-21.0	4.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	7.49	6.28	7.0	0.0	21.0	-6.98	6.42	0.73	-7.0	-21.0	4.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	7.63	6.47	7.3	0.0	21.0	-6.47	6.50	0.73	-5.5	-21.0	10.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.36	6.18	0.5	0.0	21.0	-9.84	5.95	0.66	-11.0	-19.5	0.0

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 25																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.57	6.15	9.5	0.0	20.5	-4.80	5.74	0.64	-3.3	-19.5	8.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	8.52	6.24	9.0	0.0	21.0	-5.95	6.28	0.72	-6.0	-21.0	7.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	8.26	6.26	8.3	0.0	21.0	-5.83	5.94	0.66	-5.5	-19.0	4.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	4.93	6.32	1.5	0.0	21.0	-9.27	6.23	0.69	-10.5	-19.5	3.5
Week 26																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.72	6.22	9.5	0.0	20.5	-4.65	5.49	0.61	-3.0	-21.0	6.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	9.53	6.09	10.0	0.0	21.0	-4.94	6.22	0.71	-4.0	-21.0	9.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.36	6.02	9.3	0.0	21.0	-4.74	5.92	0.66	-2.7	-19.5	8.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	5.43	6.44	2.0	0.0	21.0	-8.77	6.24	0.69	-10.0	-19.5	7.5
Week 27																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.75	6.04	9.4	0.0	20.5	-4.62	5.40	0.60	-3.0	-21.0	4.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.06	6.12	11.0	0.0	21.0	-4.40	6.32	0.72	-2.0	-21.0	10.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.56	6.14	9.3	0.0	21.0	-4.53	5.83	0.65	-1.8	-18.5	5.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	6.29	6.54	4.5	0.0	21.0	-7.90	6.24	0.69	-8.5	-19.0	2.0
Week 28																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.66	6.08	9.0	0.0	20.5	-4.70	5.48	0.61	-3.0	-21.0	4.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.38	6.25	10.5	0.0	21.0	-4.09	6.22	0.71	-2.0	-21.0	10.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.00	6.09	9.3	0.0	21.0	-4.10	5.62	0.63	-1.0	-18.5	8.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	6.86	6.62	5.0	0.0	21.0	-7.33	5.99	0.67	-7.0	-19.0	3.0
Week 29																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.77	6.31	10.5	0.0	20.5	-4.60	5.50	0.61	-1.3	-21.0	4.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.01	6.23	9.5	0.0	21.0	-4.46	6.21	0.71	-2.0	-21.0	10.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.98	6.13	11.2	0.0	21.0	-4.11	6.20	0.69	-0.8	-19.0	7.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	7.66	6.50	7.0	0.0	21.0	-6.54	5.76	0.64	-6.5	-19.0	2.0
Week 30																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.86	6.30	10.5	0.0	20.5	-4.51	5.46	0.61	-2.2	-21.0	3.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.06	6.06	9.5	0.0	21.0	-4.40	6.08	0.69	-3.5	-21.0	11.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.85	6.24	10.5	0.0	21.0	-4.24	6.26	0.70	-0.5	-18.5	6.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	8.51	6.77	7.7	0.0	21.0	-5.69	6.10	0.68	-4.3	-19.0	3.0

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 31																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.24	6.53	10.8	0.0	20.5	-4.13	5.69	0.64	0.0	-21.0	7.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.55	6.06	11.5	0.0	21.0	-3.92	6.16	0.70	-1.0	-21.0	11.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.03	5.88	10.8	0.0	21.0	-4.07	5.53	0.62	-0.9	-16.0	6.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	9.01	6.72	9.5	0.0	21.0	-5.19	6.04	0.67	-4.0	-19.0	5.5
Week 32																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.27	6.55	10.5	0.0	20.5	-4.10	5.64	0.63	0.0	-21.0	4.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.46	6.07	11.5	0.0	21.0	-4.01	6.27	0.71	-1.0	-21.0	11.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.76	6.03	9.8	0.0	21.0	-4.34	6.07	0.68	0.0	-17.5	5.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	9.63	6.80	10.0	0.0	21.0	-4.57	6.20	0.69	-2.0	-19.0	8.5
Week 33																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.14	6.74	11.3	0.0	20.5	-4.23	5.96	0.67	0.0	-21.0	5.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.66	5.97	11.5	0.0	21.0	-3.81	5.66	0.65	-1.5	-21.0	9.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.32	6.09	11.0	0.0	21.0	-3.78	5.52	0.62	-0.5	-17.0	7.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.04	6.68	10.5	0.0	21.0	-4.16	6.20	0.69	0.0	-19.0	8.5
Week 34																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.91	6.67	10.8	0.0	20.5	-4.46	6.06	0.68	-0.5	-21.0	5.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.27	5.76	11.0	0.0	21.0	-4.20	5.90	0.67	-1.2	-21.0	8.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.04	5.93	10.0	0.0	21.0	-4.05	5.48	0.61	-0.8	-16.5	5.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.35	6.54	11.0	0.0	21.0	-3.85	5.95	0.66	-0.5	-19.0	4.5
Week 35																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.06	6.61	11.0	0.0	20.5	-4.31	5.91	0.66	0.0	-21.0	3.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.69	5.76	11.5	0.0	21.0	-3.78	5.56	0.63	0.0	-21.0	6.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.91	5.99	9.8	0.0	21.0	-4.19	5.48	0.61	-1.5	-17.0	5.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.15	6.31	10.5	0.0	21.0	-4.05	5.95	0.66	-1.0	-19.0	7.5
Week 36																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.85	6.76	10.8	0.0	21.0	-4.51	5.87	0.66	-1.1	-21.0	3.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.46	5.87	11.5	0.0	21.0	-4.00	5.82	0.66	-0.5	-21.0	4.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.13	6.12	10.5	0.0	21.0	-3.96	5.54	0.62	-0.5	-17.0	6.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.02	6.49	10.5	0.0	21.0	-4.18	6.04	0.67	-0.5	-19.0	8.0

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.1
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 37																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.11	6.67	11.5	0.0	21.0	-4.26	5.75	0.64	0.0	-21.0	3.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.11	5.70	10.5	0.0	21.0	-4.36	5.59	0.64	-1.0	-21.0	3.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.08	6.34	10.3	0.0	21.0	-4.02	5.77	0.64	0.0	-20.0	6.0
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.75	6.32	11.5	0.0	21.0	-3.44	5.86	0.65	0.0	-19.0	8.0
Week 38																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	9.96	6.91	10.5	0.0	21.0	-4.41	5.94	0.66	0.0	-21.0	3.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	9.95	6.08	11.5	0.0	21.0	-4.52	5.99	0.68	-0.5	-21.0	4.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.03	6.40	10.5	0.0	21.0	-4.06	5.93	0.66	-0.8	-21.0	8.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.79	6.39	11.5	0.0	21.0	-3.41	5.94	0.66	0.0	-19.0	6.5
Week 39																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.10	6.76	12.0	0.0	20.5	-4.27	5.85	0.65	0.0	-18.5	4.5
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.18	6.12	11.5	0.0	21.0	-4.29	5.95	0.68	0.0	-21.0	4.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.14	6.38	10.5	0.0	21.0	-3.95	5.81	0.65	-0.5	-17.0	10.8
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.62	6.42	11.5	0.0	21.0	-3.58	5.95	0.66	-0.5	-19.0	7.0
Week 40																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	10.46	6.55	12.3	0.0	20.5	-3.91	5.75	0.64	0.0	-18.5	4.0
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	10.26	6.29	11.5	0.0	21.0	-4.21	6.01	0.68	0.0	-21.0	3.0
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.12	6.40	9.8	0.0	21.0	-3.98	5.96	0.67	0.0	-17.0	11.5
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	10.99	6.29	11.5	0.0	21.0	-3.21	5.94	0.66	0.0	-19.0	9.9

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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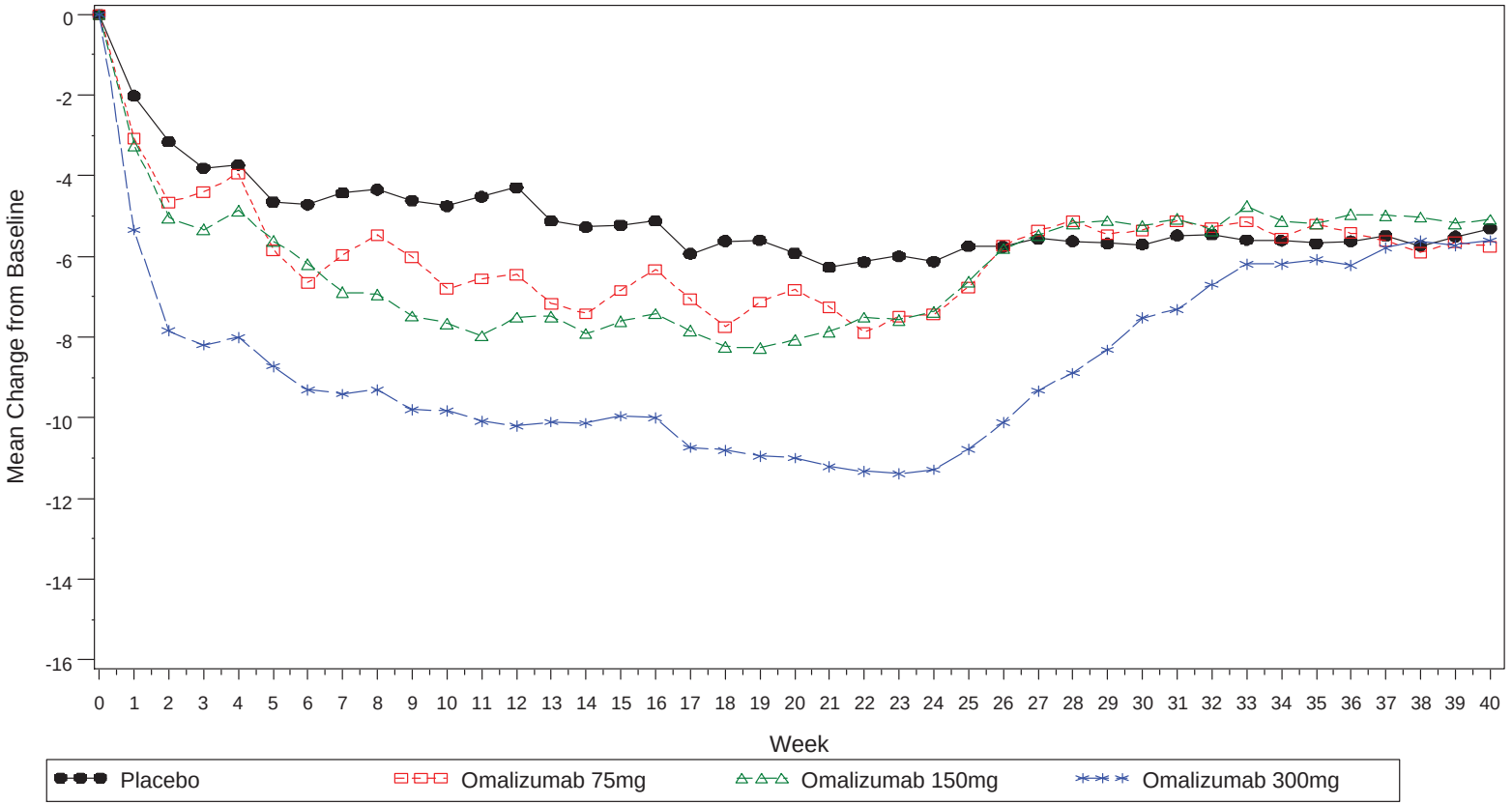
Table 14.2/35
Change from Baseline in Weekly Itch Severity Score at Week 12 (LOCF Method): Sensitivity Analysis
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Itch Severity Score				
n	80	77	80	81
Mean (SD)	-4.29 (5.25)	-6.45 (6.34)	-7.51 (6.93)	-10.19 (5.06)
SE	0.59	0.72	0.78	0.56
Median	-3.5	-6.0	-8.5	-10.5
Range	-18.5 - 7.5	-21.0 - 6.0	-21.0 - 11.0	-19.5 - 0.0
95% CI of the Mean	(-5.46, -3.12)	(-7.89, -5.01)	(-9.05, -5.96)	(-11.31, -9.08)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.29	-3.15	-5.95
95% CI of the LS Means Difference		(-4.07, -0.51)	(-4.97, -1.32)	(-7.51, -4.40)
p-value^		0.0122	0.0008	<.0001

LOCF = Last observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 14:22 Page 1 of 1

Figure 14.2/1.2
Mean Change from Baseline in Weekly Itch Severity Score by Study Week (LOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using the last observed weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/36
Change from Baseline in Weekly Itch Severity Score by Week (Mixed Effects Model): Sensitivity Analysis
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 4				
n	73	71	76	76
Treatment Difference in LS Means (VS Placebo)		-0.25	-1.19	-4.51
95% CI of the LS Means Difference		(-1.80, 1.31)	(-2.81, 0.43)	(-6.10, -2.92)
p-value		0.7557	0.1488	<.0001
Week 8				
n	67	68	69	73
Treatment Difference in LS Means (VS Placebo)		-1.11	-2.86	-5.00
95% CI of the LS Means Difference		(-2.90, 0.69)	(-4.68, -1.05)	(-6.64, -3.37)
p-value		0.2253	0.0022	<.0001
Week 12				
n	64	66	64	73
Treatment Difference in LS Means (VS Placebo)		-2.17	-3.32	-5.81
95% CI of the LS Means Difference		(-3.99, -0.34)	(-5.15, -1.50)	(-7.37, -4.24)
p-value		0.0202	0.0004	<.0001

Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
The LS mean and p-value were derived from a mixed effect model with the following covariates: baseline weekly itch severity score (original scale), and baseline weight (< 80 kg vs. >= 80 kg).

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_mixed)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/37

Change from Baseline in Weekly Itch Severity Score at Week 12 (BOCF Method for Patients Using Systemic Steroids): Sensitivity Analysis
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Itch Severity Score				
n	80	77	80	81
Mean (SD)	-3.63 (5.23)	-6.46 (6.14)	-6.47 (6.26)	-9.40 (5.73)
SE	0.58	0.70	0.70	0.64
Median	-2.3	-6.0	-5.7	-10.0
Range	-18.5 - 7.5	-21.0 - 4.0	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-4.79, -2.46)	(-7.85, -5.06)	(-7.87, -5.08)	(-10.66, -8.13)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.97	-2.79	-5.80
95% CI of the LS Means Difference		(-4.72, -1.22)	(-4.56, -1.01)	(-7.49, -4.11)
p-value^		0.0010	0.0023	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
Patients who took any systemic steroids during the 2 weeks prior to the Week 12 visit (study days 71 to 84) have Week 12 weekly itch score imputed by their baseline scores, even if they have non-missing Week 12 scores.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_sensitivity)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 1																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	27.07	8.25	28.0	8.5	42.0	-4.03	6.68	0.75	-3.0	-21.5	14.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	25.62	8.79	27.5	6.5	42.0	-6.07	8.12	0.93	-4.0	-24.0	11.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	24.00	9.97	24.8	0.5	42.0	-6.26	8.95	1.00	-4.5	-33.0	12.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	20.17	9.42	20.5	2.0	38.0	-11.15	8.76	0.97	-10.5	-33.5	3.5
Week 2																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	24.78	10.48	26.8	0.0	41.0	-6.32	9.61	1.07	-3.3	-32.0	13.1
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.03	12.24	23.5	0.0	42.0	-9.67	11.43	1.30	-8.5	-38.5	9.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	19.70	12.20	17.8	0.0	42.0	-10.57	11.42	1.28	-9.8	-39.5	8.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	14.24	12.09	14.0	0.0	42.0	-17.08	11.90	1.32	-15.5	-42.0	0.5
Week 3																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	23.51	10.09	25.0	0.0	41.0	-7.59	9.39	1.05	-5.5	-31.5	10.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.27	11.38	23.5	0.0	42.0	-9.42	10.15	1.16	-7.0	-36.5	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	18.94	12.56	19.8	0.0	42.0	-11.32	11.89	1.33	-9.0	-38.5	9.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	13.59	12.72	10.5	0.0	42.0	-17.73	12.83	1.43	-18.5	-41.0	10.0
Week 4																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	24.66	10.49	26.8	0.0	42.0	-6.44	9.05	1.01	-3.1	-31.5	13.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.51	11.98	26.0	0.0	42.0	-8.19	10.73	1.22	-5.0	-36.5	11.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	20.75	13.11	21.0	0.0	42.0	-9.51	11.86	1.33	-7.5	-40.0	16.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	14.29	12.85	13.4	0.0	42.0	-17.03	12.86	1.43	-17.0	-40.0	10.0
Week 5																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.51	11.65	24.7	0.0	41.0	-8.59	10.93	1.22	-5.9	-37.0	9.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	20.27	12.32	21.0	0.0	42.0	-11.43	11.97	1.36	-8.5	-40.3	8.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	19.09	13.21	17.8	0.0	42.0	-11.17	12.75	1.43	-8.3	-40.0	15.8
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	13.01	13.11	11.5	0.0	42.0	-18.31	12.83	1.43	-19.2	-40.0	11.0
Week 6																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.02	12.28	23.8	0.0	41.0	-9.08	11.31	1.26	-5.6	-39.0	6.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.86	12.50	16.0	0.0	42.0	-13.83	12.50	1.42	-12.5	-40.5	9.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	17.22	13.37	15.9	0.0	42.0	-13.05	12.94	1.45	-12.1	-40.0	10.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.66	12.42	8.0	0.0	42.0	-19.66	12.01	1.33	-20.0	-42.0	2.0

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 7																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.73	11.58	24.8	0.0	41.0	-8.37	10.97	1.23	-3.8	-37.0	11.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	18.73	13.27	18.0	0.0	42.0	-12.97	12.36	1.41	-13.0	-41.0	8.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.38	13.34	13.5	0.0	42.0	-14.89	12.99	1.45	-13.5	-40.0	8.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.47	12.59	4.9	0.0	42.0	-19.85	12.67	1.41	-21.5	-42.0	5.0
Week 8																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	23.31	11.83	25.3	0.0	41.0	-7.79	10.82	1.21	-4.5	-39.0	11.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	20.74	13.36	23.0	0.0	42.0	-10.95	12.43	1.42	-8.0	-42.0	9.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	16.15	13.88	15.4	0.0	42.0	-14.11	13.25	1.48	-14.5	-40.0	11.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	12.20	13.14	8.5	0.0	42.0	-19.12	13.24	1.47	-20.0	-40.3	11.1
Week 9																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.96	12.90	25.3	0.0	41.5	-8.14	11.67	1.30	-3.1	-39.0	12.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	19.83	12.51	21.0	0.0	42.0	-11.86	12.75	1.45	-8.3	-42.0	8.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.75	13.39	15.9	0.0	42.0	-14.51	13.11	1.47	-15.0	-40.0	4.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	12.69	13.19	9.5	0.0	42.0	-18.63	12.53	1.39	-20.0	-42.0	7.0
Week 10																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.86	11.94	23.8	0.0	41.5	-8.24	11.37	1.27	-5.3	-37.5	17.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.45	12.84	16.0	0.0	42.0	-14.25	13.27	1.51	-12.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.36	13.13	11.3	0.0	42.0	-15.90	13.00	1.45	-17.0	-42.0	5.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	10.71	12.68	4.5	0.0	42.0	-20.61	12.96	1.44	-24.5	-42.0	4.5
Week 11																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.95	12.29	25.0	0.0	42.0	-8.15	11.14	1.25	-2.8	-39.0	14.3
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.56	12.77	16.0	0.0	42.0	-14.13	12.87	1.47	-12.5	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.01	13.33	13.1	0.0	42.0	-16.25	13.34	1.49	-16.0	-42.0	4.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	10.35	12.19	4.0	0.0	42.0	-20.97	12.58	1.40	-24.0	-42.0	8.5
Week 12																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	23.09	12.55	24.0	0.0	41.5	-8.01	11.47	1.28	-4.0	-39.0	14.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.87	12.99	17.0	0.0	42.0	-13.82	13.26	1.51	-13.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.83	13.78	14.3	0.0	42.0	-14.44	12.95	1.45	-14.8	-40.0	4.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	10.57	12.28	5.6	0.0	42.0	-20.75	12.17	1.35	-22.0	-40.0	1.0

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 13																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	23.58	12.27	24.0	0.0	41.5	-7.52	11.18	1.25	-2.3	-39.0	13.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.49	13.32	17.0	0.0	42.0	-14.20	13.42	1.53	-11.5	-42.0	4.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.99	13.21	16.3	0.0	42.0	-14.27	13.31	1.49	-13.0	-40.0	4.7
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.85	13.45	5.0	0.0	42.0	-19.47	13.39	1.49	-22.0	-41.0	3.0
Week 14																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.35	12.50	21.8	0.0	42.0	-9.75	12.03	1.35	-6.8	-39.0	19.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	15.85	14.11	14.0	0.0	42.0	-15.84	14.08	1.60	-16.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.32	13.01	12.5	0.0	42.0	-15.95	12.70	1.42	-15.3	-39.5	1.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	10.77	13.30	4.0	0.0	42.0	-20.55	12.98	1.44	-24.5	-40.0	8.5
Week 15																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.20	12.45	22.0	0.0	41.5	-9.90	11.82	1.32	-6.5	-39.0	14.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.05	14.38	15.5	0.0	42.0	-14.65	14.44	1.65	-14.0	-42.0	7.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.96	13.30	14.0	0.0	42.0	-15.31	12.99	1.45	-15.8	-39.5	4.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.42	14.03	4.5	0.0	42.0	-19.91	13.81	1.53	-24.5	-40.0	11.0
Week 16																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.31	12.71	22.0	0.0	41.5	-9.79	11.95	1.34	-4.5	-39.0	9.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	18.05	14.53	14.0	0.0	42.0	-13.65	14.36	1.64	-12.0	-42.0	13.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.72	13.50	14.8	0.0	42.0	-14.54	12.59	1.41	-13.5	-40.0	3.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.11	13.50	5.0	0.0	42.0	-20.21	13.19	1.47	-23.5	-40.0	3.0
Week 17																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.29	13.02	21.5	0.0	41.5	-10.81	12.03	1.34	-7.4	-39.0	8.9
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	17.70	14.60	17.5	0.0	42.0	-14.00	14.43	1.64	-14.0	-42.0	14.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.73	13.93	13.3	0.0	42.0	-14.53	13.69	1.53	-15.3	-40.0	8.2
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.67	13.98	4.9	0.0	42.0	-19.65	13.22	1.47	-23.0	-39.0	0.0
Week 18																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.86	12.78	21.3	0.0	41.5	-10.24	11.66	1.30	-8.5	-35.0	13.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	15.40	14.53	12.0	0.0	42.0	-16.30	14.68	1.67	-18.5	-42.0	14.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.13	12.89	14.0	0.0	42.0	-16.13	12.94	1.45	-15.8	-42.0	0.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	9.54	12.57	3.0	0.0	42.0	-21.78	12.32	1.37	-25.0	-40.0	1.0

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 19																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.04	13.14	21.5	0.0	42.0	-10.06	11.90	1.33	-6.5	-35.0	16.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	16.83	14.36	15.5	0.0	42.0	-14.86	14.43	1.64	-16.5	-42.0	9.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.18	13.20	11.8	0.0	42.0	-16.08	12.99	1.45	-16.0	-42.0	2.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	8.79	12.56	2.0	0.0	42.0	-22.53	12.07	1.34	-26.0	-40.0	0.0
Week 20																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.56	13.45	21.8	0.0	42.0	-10.54	12.30	1.37	-6.5	-36.0	12.1
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	18.53	14.54	16.5	0.0	42.0	-13.17	13.91	1.58	-12.7	-42.0	9.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	14.57	13.19	13.3	0.0	42.0	-15.70	12.86	1.44	-15.8	-40.0	7.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	9.76	13.29	2.0	0.0	42.0	-21.56	12.69	1.41	-25.5	-40.0	0.0
Week 21																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.24	13.56	21.9	0.0	41.5	-10.86	12.58	1.41	-7.5	-37.3	9.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	18.16	13.73	17.5	0.0	42.0	-13.54	13.73	1.56	-12.1	-42.0	8.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	16.73	13.15	16.5	0.0	42.0	-13.53	13.26	1.48	-10.8	-42.0	7.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	9.53	13.07	2.0	0.0	42.0	-21.79	13.01	1.45	-25.5	-40.0	0.0
Week 22																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	19.53	13.73	21.0	0.0	41.5	-11.57	12.60	1.41	-8.5	-36.0	16.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	15.32	13.63	13.5	0.0	42.0	-16.37	14.03	1.60	-16.5	-42.0	9.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	16.24	14.03	15.5	0.0	42.0	-14.02	13.87	1.55	-13.5	-42.0	7.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	8.57	12.87	0.5	0.0	42.0	-22.75	12.42	1.38	-26.5	-40.0	0.0
Week 23																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	19.81	13.67	19.1	0.0	41.5	-11.29	12.74	1.42	-7.8	-36.0	15.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	16.46	14.04	14.0	0.0	42.0	-15.24	14.27	1.63	-16.0	-42.0	8.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	15.64	13.61	14.0	0.0	42.0	-14.62	13.60	1.52	-14.3	-41.0	7.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	8.27	12.85	0.0	0.0	42.0	-23.05	12.17	1.35	-26.5	-40.0	0.0
Week 24																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	19.37	13.85	21.0	0.0	41.5	-11.73	12.53	1.40	-8.8	-42.0	11.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	16.77	13.89	14.7	0.0	42.0	-14.92	13.77	1.57	-15.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	16.05	13.92	13.3	0.0	42.0	-14.21	13.33	1.49	-11.3	-40.0	10.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	9.21	13.38	0.5	0.0	42.0	-22.11	12.46	1.38	-25.5	-40.0	0.0

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 25																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.50	13.17	21.3	0.0	41.5	-10.60	12.32	1.38	-8.5	-39.0	14.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	18.87	13.59	17.5	0.0	42.0	-12.82	13.10	1.49	-11.5	-42.0	7.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	17.60	13.32	16.2	0.0	42.0	-12.66	12.30	1.38	-10.5	-39.5	3.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	10.16	13.57	2.5	0.0	42.0	-21.16	12.96	1.44	-24.5	-39.0	1.0
Week 26																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.96	13.23	22.3	0.0	41.5	-10.14	12.15	1.36	-3.8	-42.0	14.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	20.96	13.26	23.5	0.0	42.0	-10.73	13.02	1.48	-5.0	-42.0	10.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	20.04	12.81	20.4	0.0	42.0	-10.23	12.05	1.35	-7.3	-39.5	9.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	11.31	13.67	4.7	0.0	42.0	-20.01	12.93	1.44	-22.5	-39.0	7.5
Week 27																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.19	12.98	22.8	0.0	41.5	-9.91	12.18	1.36	-5.3	-42.0	13.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	21.93	13.19	24.5	0.0	42.0	-9.77	12.85	1.46	-4.5	-42.0	10.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	20.47	13.07	21.0	0.0	42.0	-9.79	11.77	1.32	-4.5	-39.5	6.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	13.05	13.71	8.5	0.0	42.0	-18.27	13.02	1.45	-21.0	-39.0	2.0
Week 28																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.60	13.02	22.5	0.0	41.5	-10.50	12.29	1.37	-8.0	-42.0	9.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.78	13.10	25.0	0.0	42.0	-8.91	12.62	1.44	-4.5	-41.5	10.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.34	12.83	22.3	0.0	42.0	-8.92	11.34	1.27	-3.5	-39.5	9.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	14.53	14.12	12.0	0.0	42.0	-16.79	12.87	1.43	-19.0	-39.0	3.0
Week 29																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	20.89	13.36	22.8	0.0	41.5	-10.21	12.37	1.38	-4.3	-42.0	10.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.59	12.93	25.0	0.0	42.0	-9.10	12.34	1.41	-5.0	-41.5	10.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.63	13.08	23.8	0.0	42.0	-8.63	12.56	1.40	-1.3	-39.5	7.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	16.34	13.85	14.5	0.0	42.0	-14.98	12.59	1.40	-16.5	-38.5	2.5
Week 30																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.00	13.47	22.8	0.0	41.5	-10.10	12.21	1.37	-4.8	-42.0	8.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.35	12.66	25.0	0.0	42.0	-9.35	12.35	1.41	-6.0	-38.0	14.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.26	13.24	23.3	0.0	42.0	-9.00	12.80	1.43	-0.5	-39.5	9.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	18.63	14.21	18.2	0.0	42.0	-12.69	13.17	1.46	-9.5	-37.5	7.5

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 31																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.89	13.79	25.5	0.0	41.5	-9.21	12.61	1.41	0.0	-42.0	17.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.49	12.65	26.0	0.0	42.0	-8.21	12.04	1.37	-1.0	-37.0	14.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.47	12.35	22.5	0.0	42.0	-8.79	11.38	1.27	-2.0	-36.0	7.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	19.47	14.38	19.5	0.0	42.0	-11.85	13.25	1.47	-7.0	-37.5	11.5
Week 32																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.14	13.74	24.0	0.0	41.5	-8.96	12.47	1.39	-0.1	-42.0	7.6
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.29	12.70	26.0	0.0	42.0	-8.40	12.16	1.39	-1.0	-42.0	14.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.26	12.89	22.3	0.0	42.0	-9.00	12.64	1.41	-0.2	-36.5	10.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	20.70	14.53	21.5	0.0	42.0	-10.63	13.43	1.49	-6.0	-38.0	15.0
Week 33																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.62	14.10	24.0	0.0	41.5	-9.48	13.11	1.47	-0.6	-42.0	11.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.61	12.36	26.0	0.0	42.0	-8.09	11.17	1.27	-2.5	-37.0	12.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	22.16	12.92	24.8	0.0	42.0	-8.11	11.75	1.31	-1.7	-37.5	12.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	21.55	14.35	25.0	0.0	42.0	-9.77	13.59	1.51	-1.5	-37.5	15.0
Week 34																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.17	14.17	23.8	0.0	41.5	-9.93	13.27	1.48	-2.4	-42.0	13.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.43	12.15	26.0	0.0	42.0	-8.26	11.49	1.31	-1.5	-42.0	11.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.95	12.45	22.8	0.0	42.0	-8.31	11.45	1.28	-1.3	-37.5	8.3
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	22.26	14.15	25.5	0.0	42.0	-9.06	13.35	1.48	-0.5	-38.0	9.0
Week 35																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.96	14.00	25.5	0.0	41.5	-9.14	12.94	1.45	-1.5	-42.0	14.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	24.03	12.01	26.0	0.0	42.0	-7.66	11.14	1.27	0.0	-42.0	9.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.77	12.67	23.6	0.0	42.0	-8.49	11.51	1.29	-2.8	-36.5	11.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	22.41	13.62	26.0	0.0	42.0	-8.92	13.04	1.45	-3.0	-38.0	13.0
Week 36																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.11	14.24	24.0	0.0	41.5	-9.99	13.03	1.46	-2.8	-42.0	17.0
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.60	12.27	26.0	0.0	42.0	-8.10	11.63	1.33	-1.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.85	13.05	22.3	0.0	42.0	-8.41	12.00	1.34	-1.0	-36.5	12.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	21.90	14.21	25.5	0.0	42.0	-9.42	13.52	1.50	-1.7	-38.0	14.5

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.1
Mean and Mean Change from Baseline in UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 37																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.58	14.00	24.0	0.0	42.0	-9.52	12.70	1.42	-2.5	-42.0	17.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.25	12.08	26.0	0.0	42.0	-8.45	11.13	1.27	-1.5	-42.0	6.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.70	13.30	23.8	0.0	42.0	-8.56	12.14	1.36	-0.5	-40.0	12.0
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	23.44	13.73	27.0	0.0	42.0	-7.89	13.24	1.47	0.0	-38.0	14.5
Week 38																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.19	14.40	23.5	0.0	42.0	-9.91	13.16	1.47	-0.5	-42.0	17.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	22.74	12.75	26.0	0.0	42.0	-8.96	12.10	1.38	-1.5	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.60	13.39	23.7	0.0	42.0	-8.66	12.39	1.39	-0.8	-42.0	15.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	23.39	13.70	26.0	0.0	42.0	-7.93	13.18	1.46	0.0	-38.0	13.0
Week 39																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	21.58	14.17	24.5	0.0	41.5	-9.52	12.86	1.44	-2.3	-39.0	14.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.02	12.85	26.0	0.0	42.0	-8.68	12.03	1.37	0.0	-42.0	7.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.99	13.34	26.0	0.0	42.0	-8.27	12.27	1.37	0.0	-37.5	20.2
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	23.06	13.66	27.0	0.0	42.0	-8.27	13.19	1.47	-0.5	-38.0	14.5
Week 40																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	22.07	13.76	24.3	0.0	41.5	-9.03	12.60	1.41	0.0	-39.0	7.5
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	23.17	13.09	26.0	0.0	42.0	-8.52	11.99	1.37	-1.0	-42.0	5.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	21.87	13.34	22.5	0.0	42.0	-8.39	12.40	1.39	0.0	-37.5	21.5
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	23.87	13.43	26.5	0.0	42.0	-7.45	12.94	1.44	0.0	-37.5	15.3

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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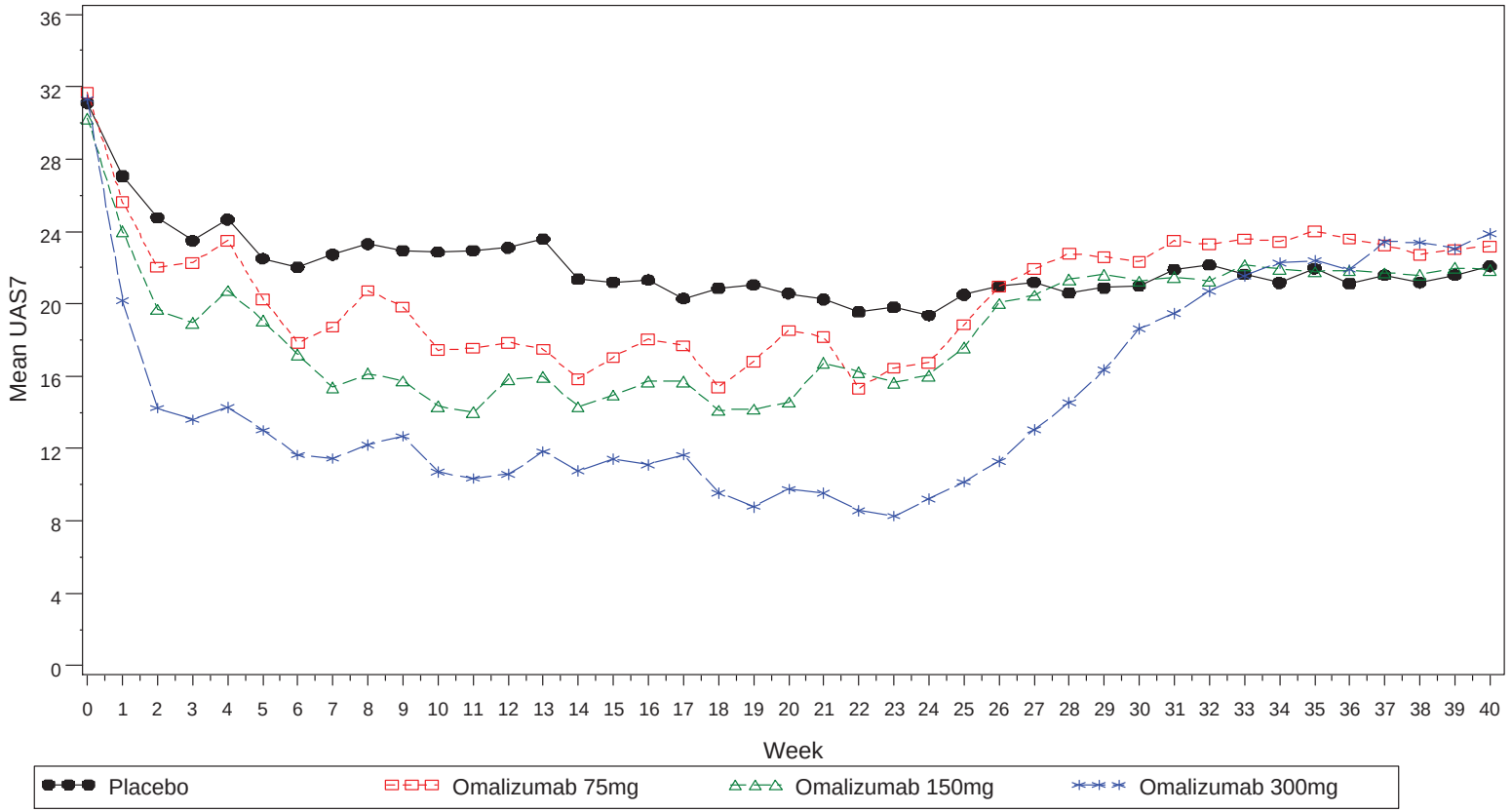
Figure 14.2/2.4
Mean UAS7 by Study Week (BOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using baseline weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_mean)
Database (CLOSED) Datasets (diaryeff)
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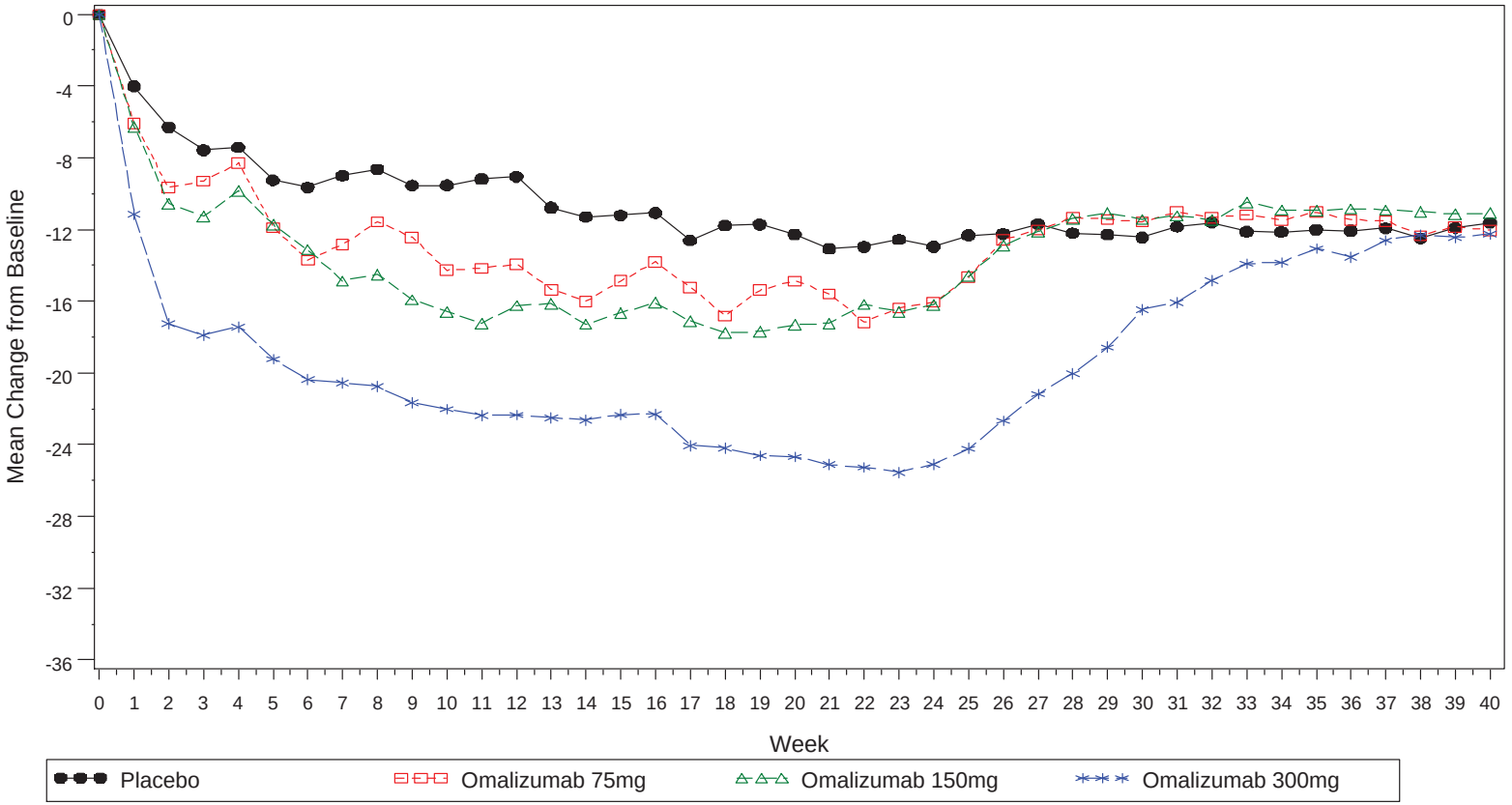
Figure 14.2/2.2
Mean Change from Baseline in UAS7 by Study Week (LOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using the last observed weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 1																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	14.73	5.24	15.0	3.5	21.0	-2.00	3.87	0.43	-1.0	-13.0	8.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	14.22	5.53	14.5	1.5	21.0	-3.00	4.63	0.53	-2.0	-17.0	6.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	13.15	5.93	14.0	0.0	21.0	-3.02	5.07	0.57	-2.0	-19.0	8.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	11.31	5.75	10.5	1.0	21.0	-5.81	4.85	0.54	-5.0	-16.5	3.0
Week 2																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	13.56	6.15	14.0	0.0	21.0	-3.17	5.35	0.60	-1.5	-17.5	8.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.23	7.17	13.0	0.0	21.0	-5.00	6.31	0.72	-4.0	-21.0	5.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.64	6.97	10.5	0.0	21.0	-5.52	6.29	0.70	-4.5	-21.0	7.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	7.75	7.02	7.0	0.0	21.0	-9.37	6.92	0.77	-8.5	-21.0	2.0
Week 3																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.93	5.99	14.0	0.0	21.0	-3.80	5.13	0.57	-2.0	-16.0	5.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.31	6.68	12.5	0.0	21.0	-4.92	5.75	0.65	-3.0	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.23	7.11	10.3	0.0	21.0	-5.94	6.63	0.74	-4.8	-21.0	5.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	7.46	7.34	4.5	0.0	21.0	-9.66	7.54	0.84	-9.0	-21.0	6.5
Week 4																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	13.48	6.11	13.8	0.0	21.0	-3.25	4.98	0.56	-1.5	-16.0	10.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.98	7.08	14.0	0.0	21.0	-4.25	6.05	0.69	-1.5	-21.0	5.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.37	7.52	12.3	0.0	21.0	-4.80	6.86	0.77	-3.7	-21.0	10.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	7.86	7.39	6.5	0.0	21.0	-9.26	7.61	0.85	-9.0	-21.0	5.5
Week 5																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.50	6.98	14.0	0.0	21.0	-4.23	6.20	0.69	-2.0	-20.0	6.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	11.44	7.09	11.1	0.0	21.0	-5.79	6.43	0.73	-4.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.21	7.52	9.0	0.0	21.0	-5.96	7.17	0.80	-4.0	-21.0	9.7
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	7.08	7.47	6.0	0.0	21.0	-10.04	7.48	0.83	-9.0	-21.0	6.5
Week 6																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.08	7.15	13.3	0.0	21.0	-4.65	6.39	0.71	-2.3	-21.0	4.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	10.14	7.16	10.5	0.0	21.0	-7.09	6.79	0.77	-6.5	-21.0	4.7
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	9.25	7.54	9.0	0.0	21.0	-6.91	7.20	0.80	-6.0	-21.0	5.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.38	7.20	3.5	0.0	21.0	-10.74	7.23	0.80	-11.0	-21.0	5.5

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 7																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.47	6.80	13.8	0.0	21.0	-4.26	6.27	0.70	-2.3	-20.5	6.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	10.31	7.62	8.8	0.0	21.0	-6.92	6.86	0.78	-7.0	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.17	7.43	7.0	0.0	21.0	-8.00	7.13	0.80	-7.0	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.29	7.35	2.5	0.0	21.0	-10.84	7.49	0.83	-12.0	-21.0	5.0
Week 8																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.79	6.95	14.0	0.0	21.0	-3.94	6.17	0.69	-1.5	-21.0	6.2
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	11.46	7.52	11.5	0.0	21.0	-5.76	6.84	0.78	-3.5	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.75	7.63	8.0	0.0	21.0	-7.42	7.19	0.80	-7.0	-21.0	4.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.45	7.36	2.5	0.0	21.0	-10.68	7.69	0.85	-11.0	-21.0	6.0
Week 9																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.34	7.54	14.0	0.0	21.0	-4.39	6.63	0.74	-1.3	-20.5	6.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	11.14	7.29	11.0	0.0	21.0	-6.09	7.04	0.80	-3.4	-21.0	3.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.56	7.62	8.5	0.0	21.0	-7.61	7.26	0.81	-6.2	-21.0	2.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.85	7.46	5.0	0.0	21.0	-10.27	7.17	0.80	-11.0	-21.0	3.0
Week 10																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.48	7.04	13.3	0.0	21.0	-4.25	6.47	0.72	-2.0	-21.0	9.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.86	7.44	8.5	0.0	21.0	-7.36	7.34	0.84	-6.0	-21.0	4.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.61	7.37	6.2	0.0	21.0	-8.56	7.18	0.80	-8.0	-21.0	2.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.68	7.35	2.0	0.0	21.0	-11.44	7.69	0.85	-12.5	-21.0	6.0
Week 11																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.44	7.13	13.5	0.0	21.0	-4.29	6.48	0.72	-1.0	-21.0	8.4
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.73	7.44	8.2	0.0	21.0	-7.50	7.25	0.83	-6.0	-21.0	5.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.44	7.37	6.5	0.0	21.0	-8.73	7.32	0.82	-8.0	-21.0	1.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.58	7.13	1.5	0.0	21.0	-11.54	7.49	0.83	-12.5	-21.0	6.0
Week 12																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.36	7.22	12.8	0.0	21.0	-4.37	6.60	0.74	-1.8	-21.0	7.3
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.86	7.51	8.5	0.0	21.0	-7.36	7.52	0.86	-5.8	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.39	7.59	7.0	0.0	21.0	-7.78	7.08	0.79	-7.3	-21.0	2.1
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.77	7.17	2.5	0.0	21.0	-11.35	7.25	0.81	-11.8	-21.0	3.0

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 13																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	12.67	7.04	14.0	0.0	21.0	-4.06	6.25	0.70	0.0	-20.5	7.3
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.73	7.81	8.5	0.0	21.0	-7.50	7.50	0.85	-6.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.44	7.48	7.3	0.0	21.0	-7.73	7.36	0.82	-7.1	-21.0	2.3
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.33	7.71	1.5	0.0	21.0	-10.80	7.75	0.86	-11.3	-21.0	3.0
Week 14																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.37	7.09	11.0	0.0	21.0	-5.36	6.86	0.77	-3.8	-21.0	11.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	8.80	8.03	7.0	0.0	21.0	-8.42	7.89	0.90	-7.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.46	7.37	6.0	0.0	21.0	-8.71	7.23	0.81	-8.3	-21.0	0.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.66	7.50	1.0	0.0	21.0	-11.46	7.52	0.84	-12.5	-21.0	2.0
Week 15																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.27	7.23	11.0	0.0	21.0	-5.46	6.83	0.76	-2.8	-21.0	9.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.39	8.02	8.5	0.0	21.0	-7.83	7.92	0.90	-7.0	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.80	7.45	7.0	0.0	21.0	-8.37	7.23	0.81	-8.0	-21.0	2.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.00	7.96	1.5	0.0	21.0	-11.13	7.99	0.89	-13.0	-21.0	5.0
Week 16																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.29	7.27	11.0	0.0	21.0	-5.44	6.66	0.74	-2.5	-21.0	5.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.88	7.99	7.0	0.0	21.0	-7.34	7.73	0.88	-5.5	-21.0	5.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.32	7.49	7.3	0.0	21.0	-7.85	6.99	0.78	-7.0	-21.0	1.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.83	7.64	0.7	0.0	21.0	-11.29	7.70	0.86	-12.5	-21.0	3.0
Week 17																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.84	7.39	9.6	0.0	21.0	-5.89	6.71	0.75	-3.8	-21.0	4.1
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.84	8.11	8.5	0.0	21.0	-7.39	7.90	0.90	-5.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.35	7.79	5.8	0.0	21.0	-7.82	7.52	0.84	-8.3	-21.0	4.1
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.07	7.83	1.0	0.0	21.0	-11.05	7.76	0.86	-12.5	-21.0	2.1
Week 18																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.21	7.39	12.0	0.0	21.0	-5.52	6.68	0.75	-3.2	-21.0	7.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	8.53	8.08	7.0	0.0	21.0	-8.69	7.93	0.90	-7.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.55	7.19	6.0	0.0	21.0	-8.62	7.18	0.80	-8.0	-21.0	1.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	4.97	7.21	0.5	0.0	21.0	-12.16	7.32	0.81	-13.5	-21.0	0.5

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 19																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.37	7.49	11.0	0.0	21.0	-5.36	6.72	0.75	-3.0	-20.5	7.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.36	8.18	7.5	0.0	21.0	-7.87	8.00	0.91	-7.0	-21.0	3.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.63	7.51	5.8	0.0	21.0	-8.54	7.16	0.80	-8.1	-21.0	1.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	4.51	7.19	0.0	0.0	21.0	-12.61	7.29	0.81	-15.0	-21.0	4.0
Week 20																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.09	7.68	10.0	0.0	21.0	-5.64	7.00	0.78	-2.5	-21.0	7.7
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	10.19	8.22	8.5	0.0	21.0	-7.04	7.72	0.88	-7.0	-21.0	4.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	7.83	7.47	6.4	0.0	21.0	-8.34	7.04	0.79	-8.0	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.06	7.50	1.0	0.0	21.0	-12.06	7.45	0.83	-14.0	-21.0	0.0
Week 21																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.89	7.75	11.0	0.0	21.0	-5.84	7.16	0.80	-3.4	-21.0	7.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	10.09	7.82	8.5	0.0	21.0	-7.14	7.48	0.85	-6.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.80	7.39	7.9	0.0	21.0	-7.37	7.24	0.81	-6.5	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.03	7.31	0.0	0.0	21.0	-12.09	7.41	0.82	-13.3	-21.0	0.0
Week 22																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.50	7.73	9.3	0.0	21.0	-6.23	7.14	0.80	-3.8	-21.0	7.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	8.44	7.76	7.0	0.0	21.0	-8.79	7.78	0.89	-7.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.69	7.98	7.3	0.0	21.0	-7.48	7.47	0.84	-7.0	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	4.42	7.11	0.0	0.0	21.0	-12.70	7.25	0.81	-14.5	-21.0	0.0
Week 23																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.69	7.72	9.3	0.0	21.0	-6.04	7.27	0.81	-3.0	-21.0	9.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.02	7.91	7.0	0.0	21.0	-8.21	7.86	0.90	-7.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.24	7.84	7.0	0.0	21.0	-7.93	7.47	0.84	-7.8	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	4.25	7.10	0.0	0.0	21.0	-12.87	7.12	0.79	-15.0	-21.0	0.0
Week 24																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.41	7.90	9.5	0.0	21.0	-6.32	7.24	0.81	-4.0	-21.0	7.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	9.28	7.94	7.6	0.0	21.0	-7.95	7.73	0.88	-7.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	8.42	7.93	6.3	0.0	21.0	-7.75	7.26	0.81	-6.8	-21.0	2.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	4.85	7.52	0.0	0.0	21.0	-12.28	7.33	0.81	-14.0	-21.0	0.5

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 25																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.93	7.59	11.3	0.0	21.0	-5.80	7.09	0.79	-4.5	-21.0	6.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	10.35	7.73	9.3	0.0	21.0	-6.88	7.34	0.84	-5.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	9.34	7.71	7.6	0.0	21.0	-6.83	6.84	0.76	-5.3	-21.0	1.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.23	7.66	1.0	0.0	21.0	-11.90	7.39	0.82	-13.5	-21.0	1.5
Week 26																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.24	7.66	11.3	0.0	21.0	-5.49	7.20	0.81	-1.3	-21.0	8.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	11.43	7.62	12.0	0.0	21.0	-5.80	7.38	0.84	-1.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.68	7.48	10.8	0.0	21.0	-5.49	6.56	0.73	-3.3	-21.0	3.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	5.88	7.63	2.0	0.0	21.0	-11.24	7.41	0.82	-12.5	-21.0	4.0
Week 27																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.44	7.54	11.8	0.0	21.0	-5.29	7.20	0.81	-1.8	-21.0	9.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	11.86	7.53	12.5	0.0	21.0	-5.37	6.97	0.79	-1.5	-21.0	3.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.91	7.48	11.4	0.0	21.0	-5.26	6.33	0.71	-2.5	-21.0	1.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	6.75	7.58	4.0	0.0	21.0	-10.37	7.38	0.82	-12.0	-21.0	0.0
Week 28																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	10.93	7.51	11.0	0.0	21.0	-5.80	7.21	0.81	-2.8	-21.0	5.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.40	7.34	13.5	0.0	21.0	-4.82	6.89	0.79	-2.0	-21.0	4.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.35	7.29	13.0	0.0	21.0	-4.82	6.09	0.68	-1.7	-21.0	1.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	7.67	8.01	5.0	0.0	21.0	-9.46	7.59	0.84	-10.0	-21.0	3.0
Week 29																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.12	7.60	11.5	0.0	21.0	-5.61	7.29	0.82	-1.8	-21.0	6.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.58	7.34	14.0	0.0	21.0	-4.64	6.69	0.76	-1.0	-21.0	4.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.64	7.46	13.3	0.0	21.0	-4.52	6.74	0.75	0.0	-21.0	5.4
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	8.69	7.83	7.5	0.0	21.0	-8.44	7.40	0.82	-9.0	-21.0	5.0
Week 30																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.14	7.74	11.8	0.0	21.0	-5.59	7.20	0.80	-1.9	-21.0	5.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.28	7.16	14.0	0.0	21.0	-4.95	6.84	0.78	-2.0	-21.0	5.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.41	7.65	13.3	0.0	21.0	-4.76	6.93	0.77	-0.7	-21.0	5.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	10.13	8.04	10.5	0.0	21.0	-7.00	7.69	0.85	-5.5	-21.0	6.5

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 31																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.65	7.81	12.8	0.0	21.0	-5.08	7.26	0.81	0.0	-21.0	10.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.94	7.19	14.0	0.0	21.0	-4.29	6.52	0.74	0.0	-21.0	4.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.45	7.09	13.0	0.0	21.0	-4.72	6.29	0.70	-1.0	-20.5	4.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	10.46	8.27	10.0	0.0	21.0	-6.66	7.83	0.87	-5.0	-21.0	6.0
Week 32																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.87	7.78	13.7	0.0	21.0	-4.87	7.18	0.80	0.0	-21.0	7.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.83	7.18	14.0	0.0	21.0	-4.39	6.45	0.73	-0.5	-21.0	4.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.51	7.37	13.0	0.0	21.0	-4.66	6.95	0.78	0.0	-21.0	6.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	11.07	8.32	12.0	0.0	21.0	-6.06	7.83	0.87	-2.0	-21.0	8.5
Week 33																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.49	7.94	13.3	0.0	21.0	-5.25	7.49	0.84	-0.1	-21.0	8.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.95	7.06	13.0	0.0	21.0	-4.28	6.12	0.70	0.0	-21.0	3.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.84	7.37	12.8	0.0	21.0	-4.33	6.65	0.74	0.0	-21.0	8.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	11.51	8.24	12.0	0.0	21.0	-5.61	7.89	0.88	-0.5	-21.0	6.5
Week 34																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.27	8.04	13.3	0.0	21.0	-5.46	7.60	0.85	-1.3	-21.0	11.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	13.16	7.21	14.0	0.0	21.0	-4.06	6.27	0.71	0.0	-21.0	3.5
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.91	7.22	13.3	0.0	21.0	-4.26	6.50	0.73	0.0	-21.0	7.5
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	11.91	8.12	12.3	0.0	21.0	-5.21	7.84	0.87	0.0	-21.0	7.5
Week 35																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.90	8.06	13.8	0.0	21.0	-4.83	7.51	0.84	0.0	-21.0	12.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	13.34	6.97	14.5	0.0	21.0	-3.88	6.13	0.70	0.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.87	7.32	13.2	0.0	21.0	-4.30	6.48	0.72	-0.3	-21.0	8.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	12.25	7.83	13.5	0.0	21.0	-4.87	7.55	0.84	-0.5	-21.0	8.5
Week 36																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.26	7.97	12.5	0.0	21.0	-5.47	7.58	0.85	-1.0	-21.0	13.5
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	13.13	6.94	14.0	0.0	21.0	-4.09	6.19	0.71	0.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.72	7.42	12.7	0.0	21.0	-4.45	6.87	0.77	0.0	-21.0	7.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	11.89	8.19	13.5	0.0	21.0	-5.24	7.85	0.87	-1.3	-21.0	8.5

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.1
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 37																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.47	7.81	12.6	0.0	21.0	-5.27	7.37	0.82	-2.0	-21.0	14.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	13.14	6.97	14.0	0.0	21.0	-4.09	5.97	0.68	-0.5	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.63	7.49	13.0	0.0	21.0	-4.54	6.85	0.77	-0.5	-21.0	6.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	12.68	7.99	14.5	0.0	21.0	-4.44	7.70	0.86	0.0	-21.0	8.0
Week 38																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.23	7.91	12.8	0.0	21.0	-5.50	7.58	0.85	-0.5	-21.0	14.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.78	7.30	14.0	0.0	21.0	-4.44	6.56	0.75	0.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.57	7.65	13.3	0.0	21.0	-4.60	6.94	0.78	0.0	-21.0	7.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	12.60	7.91	14.5	0.0	21.0	-4.52	7.59	0.84	0.0	-21.0	8.0
Week 39																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.48	7.81	13.0	0.0	21.0	-5.25	7.33	0.82	-1.2	-21.0	12.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.84	7.28	14.0	0.0	21.0	-4.39	6.43	0.73	0.0	-21.0	3.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.85	7.55	14.0	0.0	21.0	-4.32	6.96	0.78	0.0	-21.0	9.3
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	12.44	7.88	14.0	0.0	21.0	-4.68	7.58	0.84	0.0	-21.0	9.5
Week 40																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	11.61	7.68	12.9	0.0	21.0	-5.12	7.19	0.80	0.0	-21.0	6.0
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	12.91	7.34	14.0	0.0	21.0	-4.32	6.34	0.72	-0.5	-21.0	2.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	11.75	7.53	13.8	0.0	21.0	-4.41	6.90	0.77	0.0	-21.0	10.0
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	12.89	7.75	14.5	0.0	21.0	-4.24	7.37	0.82	0.0	-21.0	9.0

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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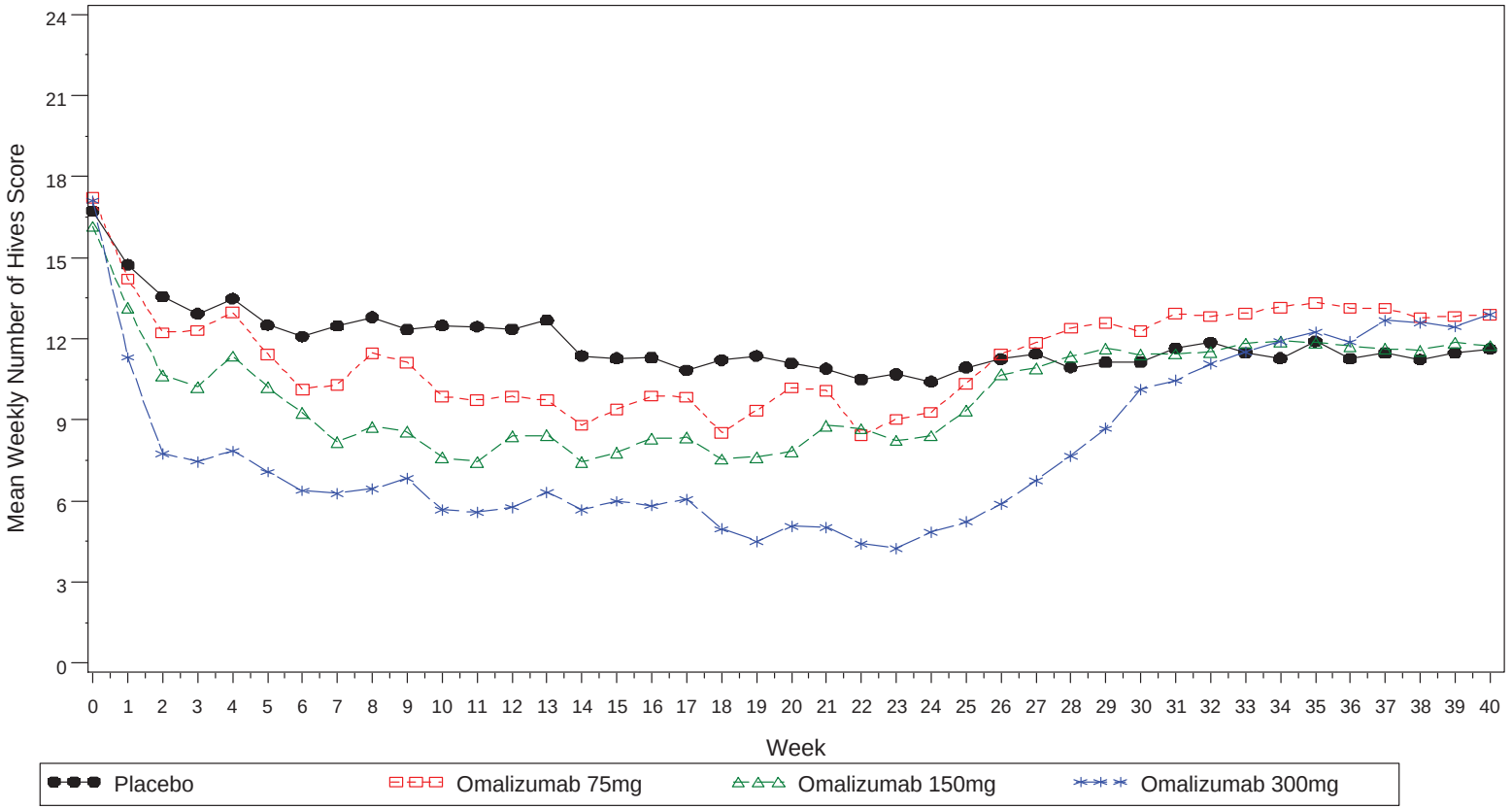
Figure 14.2/3.4
Mean Weekly Number of Hives Score by Study Week (BOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using baseline weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_mean)
Database (CLOSED) Datasets (diaryeff)
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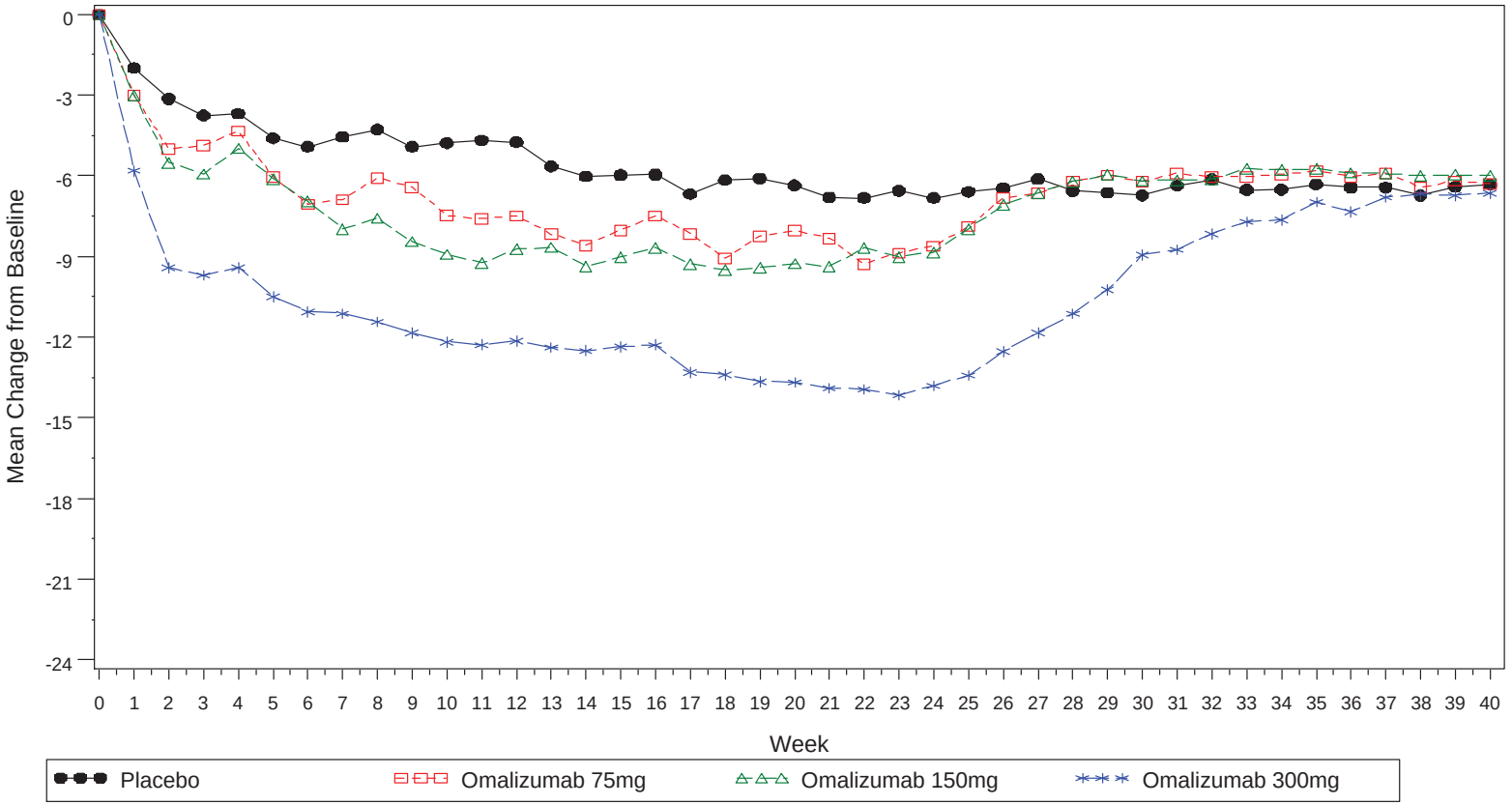
Figure 14.2/3.2
Mean Change from Baseline in Weekly Number of Hives Score by Study Week (LOCF Method)
Modified Intention to Treat Patients



Missing weekly scores are imputed using the last observed weekly scores.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 1																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	13.93	4.61	14.0	4.0	21.0	-1.71	3.23	0.36	-1.5	-9.5	6.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	13.03	4.83	13.0	1.0	21.0	-2.51	3.45	0.39	-1.5	-11.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	12.21	5.14	12.3	0.0	21.0	-3.09	4.71	0.53	-1.5	-18.0	4.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.01	5.51	10.0	2.0	21.0	-4.25	4.77	0.53	-3.0	-15.0	4.0
Week 2																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	12.91	5.60	13.5	0.0	21.0	-2.72	4.75	0.53	-1.8	-19.0	6.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.16	6.47	11.0	0.0	21.0	-4.38	5.82	0.66	-3.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.31	6.10	11.0	0.0	21.0	-4.99	6.19	0.69	-2.5	-21.0	7.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	7.97	6.51	7.5	0.0	21.0	-7.29	6.27	0.70	-6.5	-21.0	5.5
Week 3																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	12.07	5.42	11.8	0.0	21.0	-3.57	4.92	0.55	-2.3	-19.0	6.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.80	6.14	12.0	0.0	21.0	-3.73	5.18	0.59	-3.0	-21.0	4.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	9.90	6.50	9.5	0.0	21.0	-5.40	6.41	0.72	-3.8	-21.0	7.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	7.58	6.49	7.0	0.0	21.0	-7.68	6.40	0.71	-7.0	-21.0	5.5
Week 4																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	12.30	5.48	12.5	0.0	21.0	-3.33	4.31	0.48	-2.0	-19.0	5.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.08	6.26	12.5	0.0	21.0	-3.46	5.39	0.61	-2.0	-21.0	8.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.83	6.34	11.5	0.0	21.0	-4.47	5.99	0.67	-2.8	-21.0	7.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	8.26	6.80	7.0	0.0	21.0	-7.00	6.32	0.70	-6.0	-21.0	5.0
Week 5																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.49	6.01	12.4	0.0	21.0	-4.14	5.43	0.61	-2.5	-19.0	4.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	10.80	6.32	11.0	0.0	21.0	-4.74	5.82	0.66	-3.0	-21.0	5.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.23	6.54	10.3	0.0	21.0	-5.07	6.60	0.74	-3.5	-21.0	9.8
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	7.26	6.96	7.0	0.0	21.0	-8.00	6.55	0.73	-8.5	-21.0	2.5
Week 6																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.15	6.45	11.8	0.0	21.0	-4.48	5.74	0.64	-2.8	-21.0	3.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.90	6.35	8.5	0.0	21.0	-5.64	5.85	0.67	-5.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	9.08	6.99	8.1	0.0	21.0	-6.22	7.19	0.80	-4.3	-21.0	7.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	6.45	6.51	6.0	0.0	21.0	-8.80	6.66	0.74	-9.0	-21.0	3.5

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 7																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.71	6.18	12.0	0.0	21.0	-3.93	5.39	0.60	-2.3	-20.0	3.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.86	6.74	8.5	0.0	21.0	-5.68	5.94	0.68	-5.0	-21.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.25	6.80	8.3	0.0	21.0	-7.05	7.12	0.80	-6.0	-21.0	6.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.86	6.57	3.0	0.0	21.0	-9.40	6.70	0.74	-9.5	-21.0	3.0
Week 8																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.79	6.06	12.0	0.0	21.0	-3.85	5.22	0.58	-2.5	-21.0	4.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	10.68	6.66	10.5	0.0	21.0	-4.86	5.80	0.66	-4.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.73	7.14	8.0	0.0	21.0	-6.57	7.25	0.81	-5.3	-21.0	9.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	6.52	6.84	5.3	0.0	21.0	-8.74	6.86	0.76	-8.5	-21.0	3.3
Week 9																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.39	6.49	12.5	0.0	21.0	-4.25	5.76	0.64	-2.3	-21.0	3.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	10.45	6.27	10.5	0.0	21.0	-5.09	6.10	0.70	-3.5	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.14	6.78	7.8	0.0	21.0	-7.16	7.16	0.80	-5.0	-21.0	1.8
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	6.58	6.68	6.0	0.0	21.0	-8.68	7.07	0.79	-8.5	-21.0	1.5
Week 10																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.57	6.26	11.6	0.0	21.0	-4.07	5.62	0.63	-2.5	-21.0	4.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.63	6.54	9.0	0.0	21.0	-5.91	6.48	0.74	-5.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.58	6.76	7.0	0.0	21.0	-7.72	7.24	0.81	-7.8	-21.0	6.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.50	6.73	2.0	0.0	21.0	-9.76	7.03	0.78	-10.0	-21.0	2.0
Week 11																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.68	6.38	12.5	0.0	21.0	-3.95	5.51	0.62	-2.5	-21.0	5.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.49	6.51	8.2	0.0	21.0	-6.05	6.10	0.70	-5.0	-21.0	4.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.60	6.78	7.0	0.0	21.0	-7.70	7.20	0.81	-6.5	-21.0	5.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.51	6.58	2.0	0.0	21.0	-9.75	7.01	0.78	-10.0	-21.0	2.0
Week 12																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.70	6.38	12.0	0.0	21.0	-3.93	5.44	0.61	-2.8	-21.0	4.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.33	6.75	7.5	0.0	21.0	-6.20	6.29	0.72	-4.5	-21.0	2.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.34	6.88	7.0	0.0	21.0	-6.96	6.68	0.75	-6.0	-21.0	2.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.47	6.26	4.0	0.0	21.0	-9.79	6.66	0.74	-10.5	-21.0	3.0

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 13																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.76	6.22	11.8	0.0	21.0	-3.88	5.57	0.62	-1.7	-21.0	3.7
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.39	7.02	8.0	0.0	21.0	-6.15	6.58	0.75	-4.0	-21.0	5.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.67	6.94	8.9	0.0	21.0	-6.63	6.69	0.75	-5.3	-19.5	1.8
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	6.00	6.87	2.8	0.0	21.0	-9.26	7.20	0.80	-9.6	-21.0	2.0
Week 14																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.23	6.30	11.8	0.0	21.0	-4.40	5.89	0.66	-3.0	-21.0	8.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	8.37	7.16	7.0	0.0	21.0	-7.17	7.02	0.80	-7.0	-21.0	3.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.47	6.59	7.0	0.0	21.0	-7.83	7.20	0.80	-7.5	-21.0	3.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.50	6.73	2.0	0.0	21.0	-9.76	7.02	0.78	-10.5	-21.0	3.0
Week 15																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.95	6.28	11.8	0.0	21.0	-4.69	5.89	0.66	-3.3	-21.0	2.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.02	7.25	7.5	0.0	21.0	-6.52	7.06	0.80	-6.5	-21.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.96	6.94	7.3	0.0	21.0	-7.34	7.28	0.81	-5.7	-21.0	3.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.67	6.90	2.5	0.0	21.0	-9.58	7.32	0.81	-10.5	-21.0	5.0
Week 16																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.92	6.23	11.3	0.0	21.0	-4.72	5.83	0.65	-3.8	-21.0	5.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.80	7.40	9.3	0.0	21.0	-5.73	7.25	0.83	-3.9	-21.0	11.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.44	7.02	7.8	0.0	21.0	-6.86	6.90	0.77	-5.5	-21.0	1.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.64	6.82	1.4	0.0	21.0	-9.62	7.26	0.81	-11.0	-21.0	5.5
Week 17																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.74	6.55	11.2	0.0	21.0	-4.89	5.94	0.66	-3.1	-21.0	3.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.15	7.29	7.5	0.0	21.0	-6.39	7.24	0.83	-4.5	-21.0	7.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.19	7.16	7.0	0.0	21.0	-7.11	6.96	0.78	-7.3	-21.0	3.6
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.89	7.29	2.0	0.0	21.0	-9.37	7.28	0.81	-10.5	-21.0	6.0
Week 18																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.72	6.31	10.8	0.0	21.0	-4.92	5.94	0.66	-2.5	-21.0	3.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	8.11	7.40	7.0	0.0	21.0	-7.42	7.46	0.85	-6.5	-21.0	5.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.85	6.92	7.0	0.0	21.0	-7.45	7.08	0.79	-7.0	-21.0	3.8
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.75	6.39	1.0	0.0	21.0	-10.51	6.99	0.78	-11.0	-21.0	4.5

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 19																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.15	6.57	11.5	0.0	21.0	-4.49	6.10	0.68	-1.5	-19.0	7.8
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	8.98	7.44	7.5	0.0	21.0	-6.56	7.62	0.87	-4.5	-21.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	7.52	6.84	7.0	0.0	21.0	-7.78	7.14	0.80	-7.5	-21.0	3.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.28	6.27	0.0	0.0	21.0	-10.98	6.86	0.76	-12.5	-21.0	2.0
Week 20																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.87	6.49	11.8	0.0	21.0	-4.76	6.04	0.68	-2.5	-21.0	4.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.83	7.49	8.2	0.0	21.0	-5.71	7.11	0.81	-4.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.02	6.83	7.6	0.0	21.0	-7.28	6.75	0.76	-7.2	-21.0	3.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.95	6.56	1.5	0.0	21.0	-10.31	7.18	0.80	-11.0	-21.0	4.5
Week 21																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.61	6.67	12.0	0.0	21.0	-5.03	6.24	0.70	-2.0	-21.0	2.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.39	6.87	8.5	0.0	21.0	-6.15	6.95	0.79	-4.5	-21.0	5.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	9.16	6.88	9.8	0.0	21.0	-6.14	6.86	0.77	-4.5	-21.0	3.6
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.70	6.35	0.0	0.0	21.0	-10.56	7.30	0.81	-11.5	-21.0	5.0
Week 22																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.27	6.77	10.0	0.0	21.0	-5.36	6.42	0.72	-3.3	-21.0	4.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	8.18	7.07	7.0	0.0	21.0	-7.36	7.19	0.82	-7.0	-21.0	5.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.44	7.21	8.0	0.0	21.0	-6.86	7.04	0.79	-5.8	-21.0	3.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.25	6.34	0.0	0.0	21.0	-11.01	7.08	0.79	-11.5	-21.0	4.0
Week 23																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.46	6.82	9.5	0.0	21.0	-5.18	6.53	0.73	-2.8	-21.0	7.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.08	7.38	7.0	0.0	21.0	-6.46	7.30	0.83	-5.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.38	7.20	8.5	0.0	21.0	-6.92	7.07	0.79	-5.8	-21.0	3.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.03	6.19	0.0	0.0	21.0	-11.23	6.77	0.75	-12.5	-21.0	0.0
Week 24																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.38	7.12	10.5	0.0	21.0	-5.25	6.69	0.75	-3.8	-21.0	6.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	9.21	7.49	7.5	0.0	21.0	-6.33	7.14	0.81	-5.3	-21.0	5.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	8.49	7.40	7.0	0.0	21.0	-6.81	6.94	0.78	-6.0	-21.0	5.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.51	6.55	0.0	0.0	21.0	-10.74	7.00	0.78	-11.5	-21.0	2.0

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 25																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.80	6.66	11.5	0.0	21.0	-4.84	6.38	0.71	-2.5	-21.0	5.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	10.05	7.22	9.5	0.0	21.0	-5.49	6.60	0.75	-4.0	-21.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	9.27	7.06	9.0	0.0	21.0	-6.03	6.39	0.71	-5.5	-21.0	2.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	4.83	6.55	1.0	0.0	21.0	-10.43	6.85	0.76	-12.0	-21.0	1.5
Week 26																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.13	6.73	11.8	0.0	21.0	-4.51	6.55	0.73	0.0	-21.0	4.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	10.79	6.91	11.0	0.0	21.0	-4.75	6.52	0.74	-1.8	-21.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.40	6.81	11.0	0.0	21.0	-4.90	6.42	0.72	-2.3	-21.0	8.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	5.81	6.65	3.0	0.0	21.0	-9.45	6.75	0.75	-10.0	-21.0	5.5
Week 27																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.98	6.65	11.0	0.0	21.0	-4.66	6.57	0.74	-1.3	-21.0	4.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.41	6.92	12.5	0.0	21.0	-4.13	6.67	0.76	-1.0	-21.0	9.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.75	6.98	11.3	0.0	21.0	-4.55	6.25	0.70	-1.0	-21.0	4.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	7.10	7.04	6.0	0.0	21.0	-8.16	6.64	0.74	-9.5	-21.0	5.0
Week 28																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.81	6.76	11.8	0.0	21.0	-4.83	6.43	0.72	-0.5	-21.0	2.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.86	6.91	13.5	0.0	21.0	-3.68	6.52	0.74	-0.5	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.22	6.59	11.0	0.0	21.0	-4.08	5.95	0.66	0.0	-21.0	5.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	7.64	7.23	7.0	0.0	21.0	-7.62	6.71	0.75	-8.0	-21.0	7.0
Week 29																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.12	6.96	12.5	0.0	21.0	-4.51	6.36	0.71	-1.0	-21.0	6.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.75	6.81	13.0	0.0	21.0	-3.79	6.51	0.74	-0.5	-21.0	7.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.41	6.93	11.5	0.0	21.0	-3.89	6.61	0.74	0.0	-21.0	12.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	8.40	6.99	7.0	0.0	21.0	-6.85	6.55	0.73	-6.0	-20.0	4.0
Week 30																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.79	7.00	11.0	0.0	21.0	-4.85	6.56	0.73	-0.3	-21.0	2.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.72	6.64	12.5	0.0	21.0	-3.82	6.26	0.71	-0.5	-19.5	12.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.97	7.08	11.3	0.0	21.0	-4.33	6.73	0.75	-0.8	-21.0	9.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	9.69	7.49	10.0	0.0	21.0	-5.57	6.87	0.76	-3.5	-19.8	7.0

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 31																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.36	7.16	12.5	0.0	21.0	-4.28	6.80	0.76	0.0	-21.0	7.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.18	6.72	13.4	0.0	21.0	-3.36	6.40	0.73	0.0	-19.0	12.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.56	6.49	11.8	0.0	21.0	-3.74	5.80	0.65	0.0	-21.0	5.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	9.88	7.56	9.5	0.0	21.0	-5.38	6.89	0.77	-3.0	-20.0	8.5
Week 32																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.62	7.01	13.2	0.0	21.0	-4.02	6.80	0.76	0.0	-21.0	9.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.10	6.52	13.0	0.0	21.0	-3.44	6.14	0.70	-0.5	-18.0	12.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.24	6.69	12.0	0.0	21.0	-4.06	6.13	0.69	0.0	-21.0	6.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	10.56	7.50	11.0	0.0	21.0	-4.69	6.95	0.77	-1.0	-20.0	8.0
Week 33																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.13	7.26	12.5	0.0	21.0	-4.51	7.03	0.79	0.0	-21.0	10.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.40	6.64	13.5	0.0	21.0	-3.14	5.86	0.67	0.0	-17.0	9.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.86	6.85	13.3	0.0	21.0	-3.44	5.88	0.66	0.0	-21.0	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	10.90	7.37	12.5	0.0	21.0	-4.36	6.95	0.77	0.0	-21.0	7.5
Week 34																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.89	7.41	12.5	0.0	21.0	-4.75	7.31	0.82	0.0	-21.0	11.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.33	6.44	13.5	0.0	21.0	-3.21	5.51	0.63	0.0	-15.5	9.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.80	6.63	13.0	0.0	21.0	-3.50	5.65	0.63	0.0	-21.0	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.22	7.17	12.5	0.0	21.0	-4.04	6.88	0.76	0.0	-19.5	8.5
Week 35																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.39	7.43	12.5	0.0	21.0	-4.25	7.09	0.79	0.0	-21.0	12.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.52	6.42	13.5	0.0	21.0	-3.02	5.55	0.63	0.0	-17.5	11.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.53	6.89	12.3	0.0	21.0	-3.77	5.96	0.67	0.0	-21.0	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.42	6.92	13.0	0.0	21.0	-3.84	6.60	0.73	-0.5	-21.0	8.0
Week 36																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	10.93	7.36	12.5	0.0	21.0	-4.71	7.27	0.81	0.0	-21.0	14.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.27	6.42	13.5	0.0	21.0	-3.27	5.48	0.62	0.0	-20.0	8.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.87	6.97	13.0	0.0	21.0	-3.43	5.94	0.66	0.0	-19.5	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.38	7.14	13.0	0.0	21.0	-3.88	6.70	0.74	0.0	-19.6	8.5

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.1
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (BOCF Method)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 37																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.13	7.39	12.5	0.0	21.0	-4.51	7.17	0.80	0.0	-21.0	14.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.14	6.37	13.0	0.0	21.0	-3.40	5.29	0.60	-0.5	-17.0	4.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.48	6.99	12.4	0.0	21.0	-3.82	6.03	0.67	0.0	-20.5	6.5
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.95	7.16	14.0	0.0	21.0	-3.31	6.54	0.73	0.0	-19.5	8.5
Week 38																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.09	7.34	12.5	0.0	21.0	-4.54	7.08	0.79	0.0	-21.0	14.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.87	6.49	12.5	0.0	21.0	-3.67	5.74	0.65	-0.4	-18.0	10.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.41	7.13	13.0	0.0	21.0	-3.89	6.20	0.69	0.0	-21.0	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.81	7.05	13.4	0.0	21.0	-3.45	6.46	0.72	0.0	-18.5	7.5
Week 39																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.48	7.29	12.9	0.0	21.0	-4.16	7.03	0.79	0.0	-21.0	12.0
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	12.03	6.63	13.3	0.0	21.0	-3.50	5.56	0.63	0.0	-18.7	8.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.69	7.14	13.5	0.0	21.0	-3.61	5.98	0.67	0.0	-20.5	7.8
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	11.94	7.10	14.0	0.0	21.0	-3.32	6.54	0.73	0.0	-19.5	10.5
Week 40																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	11.40	7.08	12.7	0.0	21.0	-4.24	6.62	0.74	0.0	-21.0	6.5
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	11.80	6.55	12.5	0.0	21.0	-3.74	5.64	0.64	-0.5	-21.0	2.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	11.60	7.02	12.0	0.0	21.0	-3.70	5.95	0.67	0.0	-20.5	7.0
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	12.30	6.98	14.5	0.0	21.0	-2.96	6.14	0.68	0.0	-19.5	8.5

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Overall Score

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	14.0	6.6	13.0	1.0	28.0	14.0	6.6	13.0	1.0	28.0					
Omalizumab 75mg	75	12.8	6.1	13.0	3.0	30.0	12.8	6.1	13.0	3.0	30.0					
Omalizumab 150mg	80	13.6	7.1	14.0	1.0	30.0	13.6	7.1	14.0	1.0	30.0					
Omalizumab 300mg	81	13.0	6.7	13.0	1.0	27.0	13.0	6.7	13.0	1.0	27.0					
Week 4																
Placebo	71	13.8	6.6	13.0	1.0	28.0	8.8	6.7	8.0	0.0	25.0	-5.0	6.0	-4.0	-24.0	9.0
Omalizumab 75mg	70	13.0	6.1	13.0	3.0	30.0	9.3	7.4	8.0	0.0	24.0	-3.7	5.9	-4.0	-18.0	13.0
Omalizumab 150mg	77	13.8	7.1	14.0	1.0	30.0	8.3	7.8	6.0	0.0	29.0	-5.5	7.2	-6.0	-30.0	17.0
Omalizumab 300mg	76	13.2	6.6	13.0	2.0	27.0	4.8	5.7	2.5	0.0	23.0	-8.4	7.3	-7.0	-26.0	3.0
Week 12																
Placebo	62	13.2	6.5	12.0	1.0	28.0	7.1	6.7	5.0	0.0	27.0	-6.1	6.3	-5.0	-24.0	9.0
Omalizumab 75mg	66	13.1	6.2	13.5	3.0	30.0	6.8	7.4	4.0	0.0	27.0	-6.3	6.1	-5.0	-24.0	8.0
Omalizumab 150mg	63	13.6	7.2	14.0	1.0	30.0	5.6	6.7	3.0	0.0	23.0	-8.0	7.2	-8.0	-30.0	9.0
Omalizumab 300mg	72	13.1	6.6	12.5	2.0	27.0	2.8	4.1	1.0	0.0	16.0	-10.3	7.2	-10.5	-26.0	5.0
Week 24																
Placebo	50	13.0	6.1	12.0	5.0	28.0	4.9	5.9	3.0	0.0	23.0	-8.1	5.8	-7.0	-23.0	11.0
Omalizumab 75mg	59	13.2	6.3	14.0	3.0	30.0	5.6	7.2	3.0	0.0	30.0	-7.6	6.6	-9.0	-24.0	15.0
Omalizumab 150mg	55	13.6	7.3	14.0	1.0	30.0	5.0	6.4	2.0	0.0	24.0	-8.6	6.4	-8.0	-27.0	3.0
Omalizumab 300mg	69	13.1	6.7	13.0	2.0	27.0	2.5	4.5	1.0	0.0	16.0	-10.6	7.0	-11.0	-27.0	6.0
Week 40																
Placebo	43	13.0	6.1	12.0	5.0	28.0	5.0	6.8	3.0	0.0	30.0	-7.9	8.0	-7.0	-27.0	13.0
Omalizumab 75mg	45	13.3	6.7	14.0	3.0	30.0	6.3	6.7	4.0	0.0	25.0	-7.0	5.8	-6.0	-21.0	3.0
Omalizumab 150mg	49	13.3	7.4	13.0	1.0	30.0	8.1	8.0	6.0	0.0	30.0	-5.2	6.7	-3.0	-23.0	7.0
Omalizumab 300mg	50	12.7	6.3	12.5	2.0	24.0	7.8	7.2	6.0	0.0	30.0	-4.9	8.1	-5.5	-18.0	18.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Overall Score

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	12.0		12.0	12.0	12.0	13.0		13.0	13.0	13.0	1.0		1.0	1.0	1.0
Omalizumab 75mg	2	12.5	6.4	12.5	8.0	17.0	11.0	9.9	11.0	4.0	18.0	-1.5	3.5	-1.5	-4.0	1.0
Omalizumab 150mg	4	13.0	6.2	13.0	6.0	20.0	11.5	7.2	10.5	5.0	20.0	-1.5	8.7	1.5	-14.0	5.0
Omalizumab 300mg	4	11.5	8.6	10.0	4.0	22.0	17.3	10.8	19.5	3.0	27.0	5.8	5.7	7.0	-2.0	11.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Symptoms and feelings

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	4.1	1.4	4.0	1.0	6.0	4.1	1.4	4.0	1.0	6.0					
Omalizumab 75mg	75	3.9	1.2	4.0	1.0	6.0	3.9	1.2	4.0	1.0	6.0					
Omalizumab 150mg	80	3.9	1.4	4.0	1.0	6.0	3.9	1.4	4.0	1.0	6.0					
Omalizumab 300mg	81	4.0	1.3	4.0	1.0	6.0	4.0	1.3	4.0	1.0	6.0					
Week 4																
Placebo	71	4.0	1.3	4.0	1.0	6.0	2.8	1.7	2.0	0.0	6.0	-1.2	1.7	-1.0	-5.0	3.0
Omalizumab 75mg	70	4.0	1.2	4.0	1.0	6.0	3.0	1.8	3.0	0.0	6.0	-1.0	1.7	-1.0	-5.0	3.0
Omalizumab 150mg	77	3.9	1.4	4.0	1.0	6.0	2.7	1.9	2.0	0.0	6.0	-1.2	2.0	-1.0	-6.0	3.0
Omalizumab 300mg	76	4.0	1.2	4.0	1.0	6.0	1.6	1.6	1.0	0.0	6.0	-2.4	1.8	-2.0	-6.0	2.0
Week 12																
Placebo	62	3.9	1.4	4.0	1.0	6.0	2.4	1.8	2.0	0.0	6.0	-1.5	1.7	-2.0	-6.0	2.0
Omalizumab 75mg	66	4.0	1.1	4.0	1.0	6.0	2.3	1.8	2.0	0.0	6.0	-1.8	1.8	-1.0	-6.0	3.0
Omalizumab 150mg	63	3.9	1.3	4.0	1.0	6.0	1.9	1.7	2.0	0.0	6.0	-2.0	2.0	-2.0	-6.0	2.0
Omalizumab 300mg	72	4.0	1.2	4.0	1.0	6.0	1.1	1.2	1.0	0.0	5.0	-2.9	1.6	-3.0	-6.0	1.0
Week 24																
Placebo	50	3.9	1.3	4.0	2.0	6.0	1.8	1.5	1.5	0.0	6.0	-2.1	1.6	-2.0	-6.0	2.0
Omalizumab 75mg	59	4.0	1.1	4.0	1.0	6.0	1.8	1.8	1.0	0.0	6.0	-2.2	1.6	-2.0	-6.0	1.0
Omalizumab 150mg	55	3.8	1.3	4.0	1.0	6.0	1.6	1.6	1.0	0.0	6.0	-2.2	1.7	-2.0	-6.0	1.0
Omalizumab 300mg	69	4.0	1.2	4.0	1.0	6.0	0.8	1.1	0.0	0.0	5.0	-3.2	1.6	-3.0	-6.0	0.0
Week 40																
Placebo	43	3.9	1.2	4.0	2.0	6.0	1.9	1.7	1.0	0.0	6.0	-2.0	1.7	-2.0	-6.0	2.0
Omalizumab 75mg	45	4.0	1.1	4.0	1.0	6.0	2.1	1.6	2.0	0.0	6.0	-1.9	1.5	-2.0	-5.0	0.0
Omalizumab 150mg	49	3.8	1.3	4.0	1.0	6.0	2.4	1.8	2.0	0.0	6.0	-1.3	1.8	-1.0	-6.0	3.0
Omalizumab 300mg	50	3.9	1.2	4.0	1.0	6.0	2.6	1.8	2.0	0.0	6.0	-1.4	2.0	-1.0	-6.0	4.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Symptoms and feelings

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	3.0		3.0	3.0	3.0	5.0		5.0	5.0	5.0	2.0		2.0	2.0	2.0
Omalizumab 75mg	2	4.5	2.1	4.5	3.0	6.0	4.0	2.8	4.0	2.0	6.0	-0.5	0.7	-0.5	-1.0	0.0
Omalizumab 150mg	4	4.0	1.4	3.5	3.0	6.0	4.0	0.8	4.0	3.0	5.0	0.0	1.4	0.5	-2.0	1.0
Omalizumab 300mg	4	4.3	1.3	4.0	3.0	6.0	4.5	1.7	4.5	3.0	6.0	0.3	1.3	0.0	-1.0	2.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Daily activities

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	3.1	1.8	3.0	0.0	6.0	3.1	1.8	3.0	0.0	6.0					
Omalizumab 75mg	75	2.7	1.8	3.0	0.0	6.0	2.7	1.8	3.0	0.0	6.0					
Omalizumab 150mg	80	2.9	1.8	3.0	0.0	6.0	2.9	1.8	3.0	0.0	6.0					
Omalizumab 300mg	81	2.9	1.8	3.0	0.0	6.0	2.9	1.8	3.0	0.0	6.0					
Week 4																
Placebo	71	3.0	1.8	3.0	0.0	6.0	1.8	1.7	1.0	0.0	6.0	-1.2	1.5	-1.0	-5.0	2.0
Omalizumab 75mg	70	2.7	1.8	3.0	0.0	6.0	2.2	2.2	2.0	0.0	6.0	-0.5	1.7	0.0	-4.0	5.0
Omalizumab 150mg	77	2.8	1.8	3.0	0.0	6.0	1.6	1.8	1.0	0.0	6.0	-1.3	1.9	-1.0	-6.0	4.0
Omalizumab 300mg	76	3.0	1.8	3.0	0.0	6.0	1.1	1.5	0.0	0.0	6.0	-1.9	2.0	-1.0	-6.0	2.0
Week 12																
Placebo	62	2.9	1.8	3.0	0.0	6.0	1.6	1.6	1.0	0.0	6.0	-1.3	1.6	-1.0	-6.0	3.0
Omalizumab 75mg	66	2.8	1.8	3.0	0.0	6.0	1.6	2.0	1.0	0.0	6.0	-1.2	1.7	-1.0	-6.0	3.0
Omalizumab 150mg	63	2.7	1.8	3.0	0.0	6.0	1.1	1.5	0.0	0.0	6.0	-1.7	1.7	-1.0	-6.0	2.0
Omalizumab 300mg	72	3.0	1.8	3.0	0.0	6.0	0.6	1.2	0.0	0.0	4.0	-2.3	1.9	-2.0	-6.0	1.0
Week 24																
Placebo	50	2.9	1.8	3.0	0.0	6.0	1.0	1.6	0.0	0.0	6.0	-1.9	1.9	-2.0	-6.0	3.0
Omalizumab 75mg	59	2.8	1.8	3.0	0.0	6.0	1.4	1.9	0.0	0.0	6.0	-1.4	1.8	-1.0	-6.0	3.0
Omalizumab 150mg	55	2.8	1.8	3.0	0.0	6.0	1.1	1.6	0.0	0.0	6.0	-1.7	1.7	-2.0	-6.0	2.0
Omalizumab 300mg	69	3.0	1.9	3.0	0.0	6.0	0.6	1.1	0.0	0.0	4.0	-2.4	1.9	-2.0	-6.0	1.0
Week 40																
Placebo	43	2.9	1.8	3.0	0.0	6.0	1.0	1.5	1.0	0.0	6.0	-1.9	2.1	-2.0	-6.0	2.0
Omalizumab 75mg	45	2.8	1.9	3.0	0.0	6.0	1.2	1.6	1.0	0.0	6.0	-1.6	1.7	-1.0	-5.0	1.0
Omalizumab 150mg	49	2.8	1.9	3.0	0.0	6.0	1.7	1.9	1.0	0.0	6.0	-1.1	1.7	-1.0	-6.0	2.0
Omalizumab 300mg	50	2.9	1.9	3.0	0.0	6.0	1.6	1.6	1.5	0.0	6.0	-1.4	2.1	-1.0	-5.0	3.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Daily activities

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	3.0		3.0	3.0	3.0	2.0		2.0	2.0	2.0	-1.0		-1.0	-1.0	-1.0
Omalizumab 75mg	2	3.5	2.1	3.5	2.0	5.0	3.5	3.5	3.5	1.0	6.0	0.0	1.4	0.0	-1.0	1.0
Omalizumab 150mg	4	2.5	0.6	2.5	2.0	3.0	3.0	1.8	3.0	1.0	5.0	0.5	1.9	0.0	-1.0	3.0
Omalizumab 300mg	4	3.0	2.9	3.0	0.0	6.0	3.8	2.9	4.5	0.0	6.0	0.8	1.0	0.5	0.0	2.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Leisure

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	2.7	1.9	2.0	0.0	6.0	2.7	1.9	2.0	0.0	6.0					
Omalizumab 75mg	75	2.7	1.7	2.0	0.0	6.0	2.7	1.7	2.0	0.0	6.0					
Omalizumab 150mg	80	2.6	1.9	2.0	0.0	6.0	2.6	1.9	2.0	0.0	6.0					
Omalizumab 300mg	81	2.2	1.8	2.0	0.0	6.0	2.2	1.8	2.0	0.0	6.0					
Week 4																
Placebo	71	2.7	1.9	3.0	0.0	6.0	1.6	1.7	1.0	0.0	6.0	-1.1	1.8	-1.0	-6.0	2.0
Omalizumab 75mg	70	2.7	1.7	2.0	0.0	6.0	1.8	1.9	1.0	0.0	6.0	-0.9	1.6	-1.0	-5.0	4.0
Omalizumab 150mg	77	2.7	1.9	2.0	0.0	6.0	1.6	1.9	1.0	0.0	6.0	-1.1	1.8	-1.0	-6.0	4.0
Omalizumab 300mg	76	2.2	1.9	2.0	0.0	6.0	0.8	1.4	0.0	0.0	6.0	-1.4	1.9	-1.0	-6.0	2.0
Week 12																
Placebo	62	2.5	1.8	2.0	0.0	6.0	1.2	1.5	1.0	0.0	6.0	-1.4	1.8	-1.0	-6.0	1.0
Omalizumab 75mg	66	2.7	1.7	2.0	0.0	6.0	1.1	1.7	0.0	0.0	6.0	-1.6	1.7	-2.0	-6.0	3.0
Omalizumab 150mg	63	2.7	1.9	2.0	0.0	6.0	0.9	1.4	0.0	0.0	5.0	-1.8	1.8	-2.0	-6.0	1.0
Omalizumab 300mg	72	2.2	1.8	2.0	0.0	6.0	0.4	0.9	0.0	0.0	4.0	-1.8	1.9	-1.0	-6.0	1.0
Week 24																
Placebo	50	2.5	1.7	2.0	0.0	6.0	0.8	1.2	0.0	0.0	4.0	-1.7	1.5	-2.0	-6.0	2.0
Omalizumab 75mg	59	2.7	1.7	2.0	0.0	6.0	1.0	1.6	0.0	0.0	6.0	-1.7	1.7	-2.0	-6.0	4.0
Omalizumab 150mg	55	2.6	1.9	2.0	0.0	6.0	0.9	1.6	0.0	0.0	6.0	-1.8	1.8	-2.0	-6.0	3.0
Omalizumab 300mg	69	2.2	1.9	2.0	0.0	6.0	0.4	1.1	0.0	0.0	4.0	-1.8	1.9	-1.0	-6.0	3.0
Week 40																
Placebo	43	2.5	1.8	2.0	0.0	6.0	0.9	1.6	0.0	0.0	6.0	-1.6	2.1	-1.0	-6.0	4.0
Omalizumab 75mg	45	2.7	1.8	2.0	0.0	6.0	1.2	1.8	0.0	0.0	6.0	-1.5	1.9	-1.0	-6.0	2.0
Omalizumab 150mg	49	2.5	1.9	2.0	0.0	6.0	1.6	2.0	1.0	0.0	6.0	-0.9	1.9	-1.0	-6.0	4.0
Omalizumab 300mg	50	2.2	1.8	2.0	0.0	6.0	1.3	1.7	1.0	0.0	6.0	-0.9	1.9	-1.0	-5.0	5.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Leisure

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	3.0		3.0	3.0	3.0	3.0		3.0	3.0	3.0	0.0		0.0	0.0	0.0
Omalizumab 75mg	2	1.0	0.0	1.0	1.0	1.0	2.0	1.4	2.0	1.0	3.0	1.0	1.4	1.0	0.0	2.0
Omalizumab 150mg	4	2.3	2.1	2.0	0.0	5.0	2.0	2.4	1.5	0.0	5.0	-0.3	1.3	0.0	-2.0	1.0
Omalizumab 300mg	4	1.5	1.9	1.0	0.0	4.0	3.8	2.6	4.5	0.0	6.0	2.3	2.1	2.5	0.0	4.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Work and School

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	1.4	1.2	1.0	0.0	3.0	1.4	1.2	1.0	0.0	3.0					
Omalizumab 75mg	75	1.3	1.1	1.0	0.0	3.0	1.3	1.1	1.0	0.0	3.0					
Omalizumab 150mg	80	1.5	1.3	1.5	0.0	3.0	1.5	1.3	1.5	0.0	3.0					
Omalizumab 300mg	81	1.5	1.2	1.0	0.0	3.0	1.5	1.2	1.0	0.0	3.0					
Week 4																
Placebo	71	1.4	1.2	1.0	0.0	3.0	0.9	1.1	1.0	0.0	3.0	-0.5	1.2	0.0	-3.0	3.0
Omalizumab 75mg	70	1.3	1.1	1.0	0.0	3.0	0.9	1.1	1.0	0.0	3.0	-0.4	1.1	0.0	-3.0	2.0
Omalizumab 150mg	77	1.5	1.3	2.0	0.0	3.0	0.8	1.1	0.0	0.0	3.0	-0.7	1.4	0.0	-3.0	3.0
Omalizumab 300mg	76	1.5	1.1	1.0	0.0	3.0	0.5	0.9	0.0	0.0	3.0	-1.0	1.2	-1.0	-3.0	2.0
Week 12																
Placebo	62	1.5	1.2	1.0	0.0	3.0	0.7	1.0	0.0	0.0	3.0	-0.8	1.3	0.0	-3.0	3.0
Omalizumab 75mg	66	1.3	1.1	1.0	0.0	3.0	0.6	1.0	0.0	0.0	3.0	-0.7	1.2	0.0	-3.0	2.0
Omalizumab 150mg	63	1.6	1.3	2.0	0.0	3.0	0.6	1.1	0.0	0.0	3.0	-1.0	1.4	-1.0	-3.0	3.0
Omalizumab 300mg	72	1.5	1.2	1.0	0.0	3.0	0.3	0.7	0.0	0.0	3.0	-1.2	1.3	-1.0	-3.0	2.0
Week 24																
Placebo	50	1.3	1.2	1.0	0.0	3.0	0.5	0.9	0.0	0.0	3.0	-0.8	1.2	-1.0	-3.0	2.0
Omalizumab 75mg	59	1.3	1.1	1.0	0.0	3.0	0.6	1.0	0.0	0.0	3.0	-0.7	1.1	0.0	-3.0	1.0
Omalizumab 150mg	55	1.6	1.3	2.0	0.0	3.0	0.5	1.0	0.0	0.0	3.0	-1.1	1.3	-1.0	-3.0	1.0
Omalizumab 300mg	69	1.5	1.2	1.0	0.0	3.0	0.3	0.7	0.0	0.0	3.0	-1.2	1.2	-1.0	-3.0	1.0
Week 40																
Placebo	43	1.3	1.2	1.0	0.0	3.0	0.4	0.8	0.0	0.0	3.0	-1.0	1.3	-1.0	-3.0	2.0
Omalizumab 75mg	45	1.4	1.2	1.0	0.0	3.0	0.7	1.1	0.0	0.0	3.0	-0.6	1.1	0.0	-3.0	1.0
Omalizumab 150mg	49	1.6	1.3	2.0	0.0	3.0	0.8	1.1	0.0	0.0	3.0	-0.8	1.3	0.0	-3.0	2.0
Omalizumab 300mg	50	1.4	1.2	1.0	0.0	3.0	0.9	1.1	0.0	0.0	3.0	-0.5	1.3	0.0	-3.0	3.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Work and School

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	2.0		2.0	2.0	2.0	2.0		2.0	2.0	2.0	0.0		0.0	0.0	0.0
Omalizumab 75mg	2	1.0	1.4	1.0	0.0	2.0	1.5	2.1	1.5	0.0	3.0	0.5	0.7	0.5	0.0	1.0
Omalizumab 150mg	4	1.5	1.3	1.5	0.0	3.0	1.0	1.4	0.5	0.0	3.0	-0.5	1.7	0.0	-3.0	1.0
Omalizumab 300mg	4	1.0	0.8	1.0	0.0	2.0	2.0	1.4	2.5	0.0	3.0	1.0	1.8	1.0	-1.0	3.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Personal relationships

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	1.9	1.7	2.0	0.0	6.0	1.9	1.7	2.0	0.0	6.0					
Omalizumab 75mg	75	1.6	1.7	1.0	0.0	6.0	1.6	1.7	1.0	0.0	6.0					
Omalizumab 150mg	80	1.8	1.7	2.0	0.0	6.0	1.8	1.7	2.0	0.0	6.0					
Omalizumab 300mg	81	1.6	1.5	1.0	0.0	6.0	1.6	1.5	1.0	0.0	6.0					
Week 4																
Placebo	71	1.9	1.7	2.0	0.0	6.0	1.1	1.6	1.0	0.0	6.0	-0.8	1.4	0.0	-6.0	3.0
Omalizumab 75mg	70	1.6	1.7	1.0	0.0	6.0	1.0	1.6	0.0	0.0	6.0	-0.6	1.5	0.0	-5.0	3.0
Omalizumab 150mg	77	1.8	1.7	2.0	0.0	6.0	1.1	1.6	0.0	0.0	6.0	-0.7	1.6	0.0	-6.0	3.0
Omalizumab 300mg	76	1.6	1.6	1.0	0.0	6.0	0.5	0.9	0.0	0.0	4.0	-1.1	1.6	-1.0	-6.0	2.0
Week 12																
Placebo	62	1.9	1.7	1.5	0.0	6.0	0.9	1.5	0.0	0.0	6.0	-1.0	1.8	-1.0	-6.0	4.0
Omalizumab 75mg	66	1.7	1.7	1.0	0.0	6.0	0.8	1.4	0.0	0.0	6.0	-0.9	1.4	-1.0	-5.0	2.0
Omalizumab 150mg	63	1.7	1.8	1.0	0.0	6.0	0.7	1.2	0.0	0.0	4.0	-1.1	1.6	-1.0	-6.0	3.0
Omalizumab 300mg	72	1.6	1.6	1.0	0.0	6.0	0.3	0.8	0.0	0.0	4.0	-1.3	1.7	-1.0	-6.0	2.0
Week 24																
Placebo	50	1.8	1.7	1.0	0.0	6.0	0.6	1.4	0.0	0.0	6.0	-1.2	1.5	-1.0	-6.0	4.0
Omalizumab 75mg	59	1.7	1.7	1.0	0.0	6.0	0.6	1.4	0.0	0.0	6.0	-1.1	1.7	-1.0	-6.0	6.0
Omalizumab 150mg	55	1.7	1.7	1.0	0.0	6.0	0.5	1.0	0.0	0.0	4.0	-1.2	1.4	-1.0	-6.0	1.0
Omalizumab 300mg	69	1.6	1.6	1.0	0.0	6.0	0.3	0.8	0.0	0.0	3.0	-1.2	1.5	-1.0	-6.0	1.0
Week 40																
Placebo	43	1.7	1.5	1.0	0.0	6.0	0.6	1.5	0.0	0.0	6.0	-1.1	2.1	-1.0	-6.0	4.0
Omalizumab 75mg	45	1.8	1.9	1.0	0.0	6.0	0.8	1.4	0.0	0.0	6.0	-1.0	1.3	-1.0	-5.0	1.0
Omalizumab 150mg	49	1.6	1.7	1.0	0.0	6.0	1.0	1.6	0.0	0.0	6.0	-0.6	1.4	0.0	-4.0	2.0
Omalizumab 300mg	50	1.5	1.5	1.0	0.0	5.0	0.9	1.5	0.0	0.0	6.0	-0.5	1.8	0.0	-5.0	5.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Personal relationships

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	1.0		1.0	1.0	1.0	1.0		1.0	1.0	1.0	0.0		0.0	0.0	0.0
Omalizumab 75mg	2	1.0	0.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	-1.0	0.0	-1.0	-1.0	-1.0
Omalizumab 150mg	4	2.8	2.5	2.5	0.0	6.0	1.3	1.9	0.5	0.0	4.0	-1.5	3.1	-0.5	-6.0	1.0
Omalizumab 300mg	4	1.5	1.9	1.0	0.0	4.0	2.3	2.2	2.0	0.0	5.0	0.8	0.5	1.0	0.0	1.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Treatment

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	79	0.7	0.8	0.0	0.0	3.0	0.7	0.8	0.0	0.0	3.0					
Omalizumab 75mg	75	0.7	0.7	1.0	0.0	3.0	0.7	0.7	1.0	0.0	3.0					
Omalizumab 150mg	80	0.9	0.9	1.0	0.0	3.0	0.9	0.9	1.0	0.0	3.0					
Omalizumab 300mg	81	0.9	0.8	1.0	0.0	3.0	0.9	0.8	1.0	0.0	3.0					
Week 4																
Placebo	71	0.7	0.9	0.0	0.0	3.0	0.4	0.7	0.0	0.0	3.0	-0.2	0.7	0.0	-2.0	2.0
Omalizumab 75mg	70	0.7	0.7	1.0	0.0	3.0	0.4	0.6	0.0	0.0	2.0	-0.3	0.8	0.0	-2.0	2.0
Omalizumab 150mg	77	0.9	0.9	1.0	0.0	3.0	0.4	0.8	0.0	0.0	3.0	-0.5	0.8	0.0	-3.0	2.0
Omalizumab 300mg	76	0.9	0.8	1.0	0.0	3.0	0.2	0.5	0.0	0.0	3.0	-0.6	0.8	-1.0	-3.0	1.0
Week 12																
Placebo	62	0.5	0.7	0.0	0.0	2.0	0.4	0.7	0.0	0.0	3.0	-0.2	0.7	0.0	-2.0	2.0
Omalizumab 75mg	66	0.7	0.8	1.0	0.0	3.0	0.4	0.7	0.0	0.0	3.0	-0.3	0.7	0.0	-2.0	2.0
Omalizumab 150mg	63	0.9	0.9	1.0	0.0	3.0	0.4	0.9	0.0	0.0	3.0	-0.5	0.9	0.0	-3.0	2.0
Omalizumab 300mg	72	0.8	0.9	1.0	0.0	3.0	0.1	0.3	0.0	0.0	1.0	-0.7	0.9	-1.0	-3.0	1.0
Week 24																
Placebo	50	0.5	0.7	0.0	0.0	2.0	0.2	0.6	0.0	0.0	3.0	-0.3	0.7	0.0	-2.0	2.0
Omalizumab 75mg	59	0.7	0.8	1.0	0.0	3.0	0.3	0.6	0.0	0.0	3.0	-0.5	0.9	0.0	-3.0	2.0
Omalizumab 150mg	55	1.0	1.0	1.0	0.0	3.0	0.4	0.8	0.0	0.0	3.0	-0.6	0.9	0.0	-3.0	1.0
Omalizumab 300mg	69	0.9	0.9	1.0	0.0	3.0	0.2	0.6	0.0	0.0	3.0	-0.7	1.0	-1.0	-3.0	2.0
Week 40																
Placebo	43	0.5	0.7	0.0	0.0	2.0	0.3	0.6	0.0	0.0	3.0	-0.3	0.6	0.0	-2.0	1.0
Omalizumab 75mg	45	0.7	0.8	1.0	0.0	3.0	0.2	0.5	0.0	0.0	2.0	-0.5	0.7	0.0	-3.0	1.0
Omalizumab 150mg	49	1.1	0.9	1.0	0.0	3.0	0.6	0.9	0.0	0.0	3.0	-0.4	0.8	0.0	-3.0	1.0
Omalizumab 300mg	50	0.8	0.7	1.0	0.0	2.0	0.5	0.7	0.0	0.0	3.0	-0.2	0.9	0.0	-2.0	2.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/15
Mean and Mean Change from Baseline in Dermatology Life Quality Index (DLQI) Scores by Study Week (Observed Data)
Modified Intention to Treat Patients

DLQI Domain: Treatment

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	0.0		0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0		0.0	0.0	0.0
Omalizumab 75mg	2	1.5	0.7	1.5	1.0	2.0	0.0	0.0	0.0	0.0	0.0	-1.5	0.7	-1.5	-2.0	-1.0
Omalizumab 150mg	4	0.0	0.0	0.0	0.0	0.0	0.3	0.5	0.0	0.0	1.0	0.3	0.5	0.0	0.0	1.0
Omalizumab 300mg	4	0.3	0.5	0.0	0.0	1.0	1.0	0.8	1.0	0.0	2.0	0.8	0.5	1.0	0.0	1.0

Baseline overall DLQI and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_meanchg)
Database (CLOSED) Datasets (dlqieff)
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Table 14.2/38
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Sex (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Male	28	22	16	21
Change from Baseline in Weekly Itch Severity Score				
n	28	22	16	21
Mean (SD)	-4.14 (5.28)	-6.28 (6.70)	-4.81 (5.43)	-10.44 (6.55)
SE	1.00	1.43	1.36	1.43
Median	-3.5	-2.3	-2.8	-12.5
Range	-15.5 - 7.5	-20.5 - 0.0	-16.0 - 0.0	-19.0 - 0.0
95% CI of the Mean	(-6.19, -2.09)	(-9.25, -3.30)	(-7.70, -1.91)	(-13.42, -7.46)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.41	-0.61	-5.66
95% CI of the LS Means Difference		(-5.76, 0.93)	(-4.00, 2.79)	(-9.22, -2.09)
p-value^		0.1531	0.7200	0.0026
Female	52	55	64	60
Change from Baseline in Weekly Itch Severity Score				
n	52	55	64	60
Mean (SD)	-3.36 (5.22)	-6.53 (5.97)	-7.12 (6.43)	-9.03 (5.44)
SE	0.72	0.80	0.80	0.70
Median	-1.3	-6.0	-7.5	-10.0
Range	-18.5 - 5.0	-21.0 - 4.0	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-4.81, -1.91)	(-8.15, -4.92)	(-8.72, -5.51)	(-10.43, -7.63)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.42	-3.89	-5.92
95% CI of the LS Means Difference		(-5.54, -1.31)	(-6.03, -1.76)	(-7.92, -3.92)
p-value^		0.0018	0.0005	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_sex)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/39
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Age (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
<18	4	5	7	2
Change from Baseline in Weekly Itch Severity Score				
n	4	5	7	2
Mean (SD)	-3.38 (5.79)	-1.85 (3.11)	-5.09 (4.41)	-7.38 (5.83)
SE	2.90	1.39	1.67	4.13
Median	-3.8	0.0	-3.6	-7.4
Range	-9.0 - 3.0	-7.2 - 0.0	-10.0 - 0.0	-11.5 - -3.3
95% CI of the Mean	(-12.59, 5.84)	(-5.71, 2.01)	(-9.17, -1.01)	(-59.79, 45.04)
Treatment Difference in LS Means* (relative to the Placebo group)		1.88	-1.59	NE
95% CI of the LS Means Difference		(-5.77, 9.53)	(-7.93, 4.75)	(NE, NE)
p-value^		0.5553	0.5715	NE
18-64	71	68	70	76
Change from Baseline in Weekly Itch Severity Score				
n	71	68	70	76
Mean (SD)	-3.60 (5.18)	-6.67 (6.33)	-6.80 (6.53)	-9.45 (5.86)
SE	0.61	0.77	0.78	0.67
Median	-2.5	-6.0	-6.0	-10.1
Range	-18.5 - 7.5	-21.0 - 4.0	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-4.83, -2.38)	(-8.20, -5.14)	(-8.36, -5.25)	(-10.79, -8.11)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.25	-3.00	-5.79
95% CI of the LS Means Difference		(-5.13, -1.36)	(-4.92, -1.09)	(-7.59, -3.99)
p-value^		0.0009	0.0023	<.0001
>=65	5	4	3	3
Change from Baseline in Weekly Itch Severity Score				
n	5	4	3	3

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_age)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/39
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Age (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	-4.30 (6.59)	-8.63 (2.50)	-6.83 (4.25)	-9.33 (2.36)
SE	2.95	1.25	2.46	1.36
Median	-1.0	-8.0	-8.5	-8.5
Range	-15.5 - 0.0	-12.0 - -6.5	-10.0 - -2.0	-12.0 - -7.5
95% CI of the Mean	(-12.48, 3.88)	(-12.60, -4.65)	(-17.40, 3.73)	(-15.20, -3.46)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.22	-5.11	-10.32
95% CI of the LS Means Difference		(-9.51, 5.07)	(-17.73, 7.52)	(-17.64, -2.99)
p-value^		0.4690	0.3242	0.0174

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_age)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/40
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Race (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
White	64	62	63	74
Change from Baseline in Weekly Itch Severity Score				
n	64	62	63	74
Mean (SD)	-3.45 (5.33)	-6.90 (6.20)	-7.24 (6.20)	-9.32 (5.74)
SE	0.67	0.79	0.78	0.67
Median	-1.5	-7.0	-7.0	-10.0
Range	-18.5 - 7.5	-21.0 - 4.0	-21.0 - 3.0	-19.5 - 0.0
95% CI of the Mean	(-4.78, -2.12)	(-8.47, -5.33)	(-8.80, -5.68)	(-10.65, -7.99)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.48	-3.83	-6.01
95% CI of the LS Means Difference		(-5.49, -1.48)	(-5.81, -1.84)	(-7.87, -4.15)
p-value^		0.0008	0.0002	<.0001
Black or African-American	10	9	9	5
Change from Baseline in Weekly Itch Severity Score				
n	10	9	9	5
Mean (SD)	-2.56 (4.25)	-5.11 (5.21)	-1.10 (4.49)	-7.63 (5.02)
SE	1.34	1.74	1.50	2.24
Median	-1.8	-4.5	0.0	-7.0
Range	-10.5 - 4.0	-14.0 - 0.0	-10.5 - 5.0	-13.4 - -1.8
95% CI of the Mean	(-5.60, 0.48)	(-9.11, -1.11)	(-4.55, 2.35)	(-13.86, -1.40)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.43	1.74	-3.81
95% CI of the LS Means Difference		(-7.78, 0.92)	(-2.27, 5.75)	(-9.51, 1.89)
p-value^		0.1132	0.3699	0.1689
Other	6	6	8	2
Change from Baseline in Weekly Itch Severity Score				
n	6	6	8	2

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_race)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/40
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Race (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	-7.42 (4.57)	-3.92 (6.95)	-8.31 (5.98)	-16.50 (2.12)
SE	1.86	2.84	2.11	1.50
Median	-9.0	-0.3	-8.8	-16.5
Range	-12.5 - 0.0	-15.5 - 1.5	-15.0 - 0.0	-18.0 - -15.0
95% CI of the Mean	(-12.21, -2.63)	(-11.21, 3.37)	(-13.31, -3.32)	(-35.56, 2.56)
Treatment Difference in LS Means* (relative to the Placebo group)		4.56	0.05	-6.71
95% CI of the LS Means Difference		(-4.61, 13.73)	(-7.06, 7.15)	(-18.90, 5.48)
p-value^		0.2849	0.9889	0.2013

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_race)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/41
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Region (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
US	54	55	56	54
Change from Baseline in Weekly Itch Severity Score				
n	54	55	56	54
Mean (SD)	-4.05 (5.04)	-5.22 (5.64)	-5.80 (6.38)	-9.15 (5.58)
SE	0.69	0.76	0.85	0.76
Median	-3.8	-4.5	-4.6	-9.8
Range	-18.5 - 4.0	-20.5 - 1.5	-21.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-5.43, -2.67)	(-6.75, -3.70)	(-7.51, -4.10)	(-10.67, -7.63)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.39	-1.79	-5.33
95% CI of the LS Means Difference		(-3.40, 0.61)	(-3.92, 0.35)	(-7.32, -3.35)
p-value^		0.1718	0.1000	<.0001
Non-US	26	22	24	27
Change from Baseline in Weekly Itch Severity Score				
n	26	22	24	27
Mean (SD)	-2.77 (5.59)	-9.55 (6.38)	-8.64 (5.69)	-9.89 (6.12)
SE	1.10	1.36	1.16	1.18
Median	-0.8	-9.3	-8.5	-11.0
Range	-15.5 - 7.5	-21.0 - 4.0	-20.0 - 0.0	-19.5 - 0.0
95% CI of the Mean	(-5.03, -0.51)	(-12.37, -6.72)	(-11.04, -6.24)	(-12.31, -7.47)
Treatment Difference in LS Means* (relative to the Placebo group)		-7.04	-5.79	-6.75
95% CI of the LS Means Difference		(-10.43, -3.65)	(-9.01, -2.58)	(-10.14, -3.37)
p-value^		0.0001	0.0007	0.0002

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_region)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/42
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Baseline Itch Severity Score (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
<13	26	28	26	28
Change from Baseline in Weekly Itch Severity Score				
n	26	28	26	28
Mean (SD)	-2.10 (4.43)	-3.96 (4.13)	-4.67 (4.13)	-7.67 (3.49)
SE	0.87	0.78	0.81	0.66
Median	-2.0	-3.3	-4.5	-8.5
Range	-10.5 - 7.5	-11.5 - 4.0	-11.0 - 5.0	-12.5 - 0.0
95% CI of the Mean	(-3.89, -0.31)	(-5.56, -2.35)	(-6.34, -3.00)	(-9.02, -6.31)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.78	-1.77	-5.10
95% CI of the LS Means Difference		(-4.26, 0.69)	(-4.19, 0.65)	(-7.39, -2.80)
p-value^		0.1544	0.1483	<.0001
>=13	54	49	54	53
Change from Baseline in Weekly Itch Severity Score				
n	54	49	54	53
Mean (SD)	-4.37 (5.45)	-7.89 (6.66)	-7.61 (6.92)	-10.31 (6.47)
SE	0.74	0.95	0.94	0.89
Median	-2.5	-7.8	-8.3	-12.0
Range	-18.5 - 2.4	-21.0 - 1.5	-21.0 - 3.0	-19.5 - 0.0
95% CI of the Mean	(-5.86, -2.89)	(-9.80, -5.98)	(-9.50, -5.72)	(-12.09, -8.53)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.49	-3.27	-5.94
95% CI of the LS Means Difference		(-5.88, -1.11)	(-5.66, -0.88)	(-8.24, -3.64)
p-value^		0.0046	0.0077	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_base)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/43
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Baseline UAS7 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
< Median	38	36	43	40
Change from Baseline in Weekly Itch Severity Score				
n	38	36	43	40
Mean (SD)	-2.63 (4.81)	-4.74 (4.70)	-5.99 (5.34)	-8.10 (4.59)
SE	0.78	0.78	0.81	0.73
Median	-1.5	-3.8	-5.5	-8.5
Range	-13.0 - 7.5	-14.5 - 4.0	-16.0 - 5.0	-16.5 - 0.0
95% CI of the Mean	(-4.21, -1.05)	(-6.33, -3.14)	(-7.63, -4.34)	(-9.57, -6.63)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.43	-3.39	-5.61
95% CI of the LS Means Difference		(-4.64, -0.23)	(-5.59, -1.19)	(-7.70, -3.53)
p-value^		0.0310	0.0030	<.0001
>= Median	42	41	37	41
Change from Baseline in Weekly Itch Severity Score				
n	42	41	37	41
Mean (SD)	-4.54 (5.48)	-7.97 (6.88)	-7.43 (7.22)	-10.66 (6.47)
SE	0.85	1.07	1.19	1.01
Median	-3.0	-7.0	-7.0	-12.0
Range	-18.5 - 1.0	-21.0 - 1.5	-21.0 - 3.0	-19.5 - 0.0
95% CI of the Mean	(-6.25, -2.83)	(-10.14, -5.80)	(-9.84, -5.03)	(-12.71, -8.62)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.46	-2.81	-5.98
95% CI of the LS Means Difference		(-6.19, -0.74)	(-5.72, 0.10)	(-8.64, -3.32)
p-value^		0.0134	0.0582	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_uas)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/44
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Body Weight (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
<80 Kg	35	38	40	45
Change from Baseline in Weekly Itch Severity Score				
n	35	38	40	45
Mean (SD)	-3.77 (5.23)	-6.09 (5.79)	-7.69 (5.47)	-9.48 (5.26)
SE	0.88	0.94	0.87	0.78
Median	-1.5	-6.8	-8.3	-10.0
Range	-18.5 - 3.0	-20.0 - 4.0	-18.5 - 1.5	-19.5 - 0.0
95% CI of the Mean	(-5.57, -1.98)	(-8.00, -4.19)	(-9.44, -5.94)	(-11.06, -7.90)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.97	-4.25	-5.99
95% CI of the LS Means Difference		(-5.56, -0.39)	(-6.75, -1.76)	(-8.38, -3.61)
p-value^		0.0249	0.0011	<.0001
>=80 Kg	45	39	40	36
Change from Baseline in Weekly Itch Severity Score				
n	45	39	40	36
Mean (SD)	-3.53 (5.28)	-6.82 (6.52)	-5.62 (6.91)	-9.30 (6.36)
SE	0.79	1.04	1.09	1.06
Median	-2.5	-6.0	-2.8	-10.5
Range	-15.5 - 7.5	-21.0 - 1.5	-21.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-5.11, -1.94)	(-8.93, -4.70)	(-7.83, -3.41)	(-11.45, -7.15)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.91	-1.56	-5.37
95% CI of the LS Means Difference		(-5.42, -0.40)	(-4.14, 1.02)	(-7.89, -2.86)
p-value^		0.0235	0.2332	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_bwt)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/45
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Positive CU Index (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Yes	25	18	16	21
Change from Baseline in Weekly Itch Severity Score				
n	25	18	16	21
Mean (SD)	-3.01 (4.92)	-7.80 (7.44)	-3.56 (6.67)	-7.38 (5.41)
SE	0.98	1.75	1.67	1.18
Median	-2.5	-8.3	0.0	-7.5
Range	-15.5 - 7.5	-20.5 - 4.0	-16.0 - 3.0	-16.0 - 0.0
95% CI of the Mean	(-5.04, -0.97)	(-11.50, -4.10)	(-7.12, -0.01)	(-9.84, -4.91)
Treatment Difference in LS Means* (relative to the Placebo group)		-4.19	0.06	-4.14
95% CI of the LS Means Difference		(-7.96, -0.42)	(-3.69, 3.81)	(-7.27, -1.01)
p-value^		0.0303	0.9739	0.0107
No	55	59	63	60
Change from Baseline in Weekly Itch Severity Score				
n	55	59	63	60
Mean (SD)	-3.92 (5.38)	-6.05 (5.70)	-7.55 (5.96)	-10.10 (5.72)
SE	0.73	0.74	0.75	0.74
Median	-2.0	-5.9	-8.0	-10.5
Range	-18.5 - 5.0	-21.0 - 1.5	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-5.37, -2.47)	(-7.54, -4.57)	(-9.05, -6.05)	(-11.58, -8.63)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.46	-3.80	-6.38
95% CI of the LS Means Difference		(-4.51, -0.41)	(-5.85, -1.75)	(-8.44, -4.32)
p-value^		0.0191	0.0004	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_auto)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/46

Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Presence of Angioedema (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Yes	44	35	38	34
Change from Baseline in Weekly Itch Severity Score				
n	44	35	38	34
Mean (SD)	-3.29 (4.85)	-6.46 (6.52)	-5.18 (5.94)	-9.60 (6.33)
SE	0.73	1.10	0.96	1.09
Median	-1.8	-5.0	-3.1	-10.8
Range	-18.5 - 4.0	-20.0 - 4.0	-15.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-4.76, -1.81)	(-8.70, -4.22)	(-7.13, -3.23)	(-11.81, -7.39)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.41	-1.93	-6.48
95% CI of the LS Means Difference		(-5.91, -0.91)	(-4.30, 0.44)	(-9.00, -3.96)
p-value^		0.0081	0.1091	<.0001
No	36	42	42	47
Change from Baseline in Weekly Itch Severity Score				
n	36	42	42	47
Mean (SD)	-4.06 (5.69)	-6.46 (5.89)	-7.99 (6.35)	-9.25 (5.33)
SE	0.95	0.91	0.98	0.78
Median	-2.5	-6.3	-8.0	-10.0
Range	-14.5 - 7.5	-21.0 - 1.5	-21.0 - 0.5	-19.5 - 0.0
95% CI of the Mean	(-5.98, -2.13)	(-8.30, -4.63)	(-9.97, -6.01)	(-10.82, -7.69)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.49	-3.51	-4.98
95% CI of the LS Means Difference		(-5.13, 0.16)	(-6.16, -0.86)	(-7.41, -2.55)
p-value^		0.0649	0.0101	0.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_bangio)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/47

Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Previous Use of Systemic Steroids (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Yes	31	41	32	36
Change from Baseline in Weekly Itch Severity Score				
n	31	41	32	36
Mean (SD)	-3.86 (5.28)	-6.50 (6.23)	-7.39 (5.90)	-9.84 (5.67)
SE	0.95	0.97	1.04	0.94
Median	-2.5	-5.9	-7.8	-11.0
Range	-18.5 - 3.0	-21.0 - 1.5	-21.0 - 0.5	-19.5 - 0.0
95% CI of the Mean	(-5.79, -1.92)	(-8.46, -4.53)	(-9.52, -5.26)	(-11.75, -7.92)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.08	-3.85	-5.99
95% CI of the LS Means Difference		(-5.82, -0.34)	(-6.66, -1.05)	(-8.65, -3.32)
p-value^		0.0282	0.0078	<.0001
No	49	36	48	45
Change from Baseline in Weekly Itch Severity Score				
n	49	36	48	45
Mean (SD)	-3.49 (5.24)	-6.42 (6.13)	-6.16 (6.53)	-9.05 (5.83)
SE	0.75	1.02	0.94	0.87
Median	-2.0	-6.3	-4.5	-9.0
Range	-15.5 - 7.5	-20.0 - 4.0	-20.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-5.00, -1.99)	(-8.49, -4.34)	(-8.06, -4.27)	(-10.80, -7.30)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.66	-2.36	-5.42
95% CI of the LS Means Difference		(-5.18, -0.15)	(-4.72, -0.00)	(-7.72, -3.11)
p-value^		0.0380	0.0499	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_psmed)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/48

Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Level of Thyroperoxidase Antibody (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
High (>34.99 U/Ml)	12	16	10	9
Change from Baseline in Weekly Itch Severity Score				
n	12	16	10	9
Mean (SD)	-5.46 (5.29)	-7.72 (5.31)	-5.65 (5.51)	-9.83 (5.05)
SE	1.53	1.33	1.74	1.68
Median	-4.5	-8.3	-5.5	-11.0
Range	-18.5 - 0.0	-16.5 - 0.0	-16.0 - 1.5	-15.5 - 0.0
95% CI of the Mean	(-8.82, -2.10)	(-10.55, -4.89)	(-9.59, -1.71)	(-13.71, -5.95)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.24	-0.24	-4.10
95% CI of the LS Means Difference		(-6.37, 1.89)	(-5.27, 4.79)	(-9.27, 1.07)
p-value^		0.2741	0.9221	0.1124
Normal (<=34.99 U/Ml)	67	58	70	72
Change from Baseline in Weekly Itch Severity Score				
n	67	58	70	72
Mean (SD)	-3.36 (5.21)	-6.34 (6.40)	-6.80 (6.40)	-9.34 (5.84)
SE	0.64	0.84	0.77	0.69
Median	-1.5	-5.5	-6.3	-10.0
Range	-15.5 - 7.5	-21.0 - 4.0	-21.0 - 5.0	-19.5 - 0.0
95% CI of the Mean	(-4.63, -2.09)	(-8.03, -4.66)	(-8.33, -5.27)	(-10.72, -7.97)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.15	-3.32	-6.08
95% CI of the LS Means Difference		(-5.14, -1.15)	(-5.23, -1.41)	(-7.93, -4.24)
p-value^		0.0022	0.0008	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_thyro)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/49
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Duration of Disease (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
<2 years	26	29	24	34
Change from Baseline in Weekly Itch Severity Score				
n	26	29	24	34
Mean (SD)	-2.95 (4.07)	-6.10 (5.76)	-6.13 (6.35)	-9.71 (6.34)
SE	0.80	1.07	1.30	1.09
Median	-2.0	-5.0	-5.7	-9.5
Range	-15.5 - 2.4	-20.5 - 1.5	-20.0 - 3.0	-19.5 - 0.0
95% CI of the Mean	(-4.60, -1.31)	(-8.29, -3.91)	(-8.81, -3.45)	(-11.92, -7.50)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.75	-2.89	-6.78
95% CI of the LS Means Difference		(-6.42, -1.08)	(-5.87, 0.09)	(-9.58, -3.98)
p-value^		0.0069	0.0574	<.0001
2-10 years	36	31	34	31
Change from Baseline in Weekly Itch Severity Score				
n	36	31	34	31
Mean (SD)	-4.82 (5.58)	-8.16 (6.72)	-7.48 (5.78)	-9.79 (5.54)
SE	0.93	1.21	0.99	1.00
Median	-3.8	-7.5	-8.3	-10.5
Range	-18.5 - 5.0	-21.0 - 1.0	-16.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-6.71, -2.93)	(-10.63, -5.70)	(-9.50, -5.46)	(-11.83, -7.76)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.23	-3.14	-5.16
95% CI of the LS Means Difference		(-6.19, -0.28)	(-5.75, -0.52)	(-7.86, -2.47)
p-value^		0.0325	0.0194	0.0003
>10 years	16	16	20	16
Change from Baseline in Weekly Itch Severity Score				
n	16	16	20	16

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_dciuc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/49
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Duration of Disease (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	-2.53 (6.03)	-4.45 (4.60)	-5.85 (7.05)	-7.96 (4.78)
SE	1.51	1.15	1.58	1.20
Median	-0.5	-4.5	-2.5	-7.8
Range	-14.5 - 7.5	-14.0 - 1.5	-21.0 - 1.5	-14.5 - 0.0
95% CI of the Mean	(-5.74, 0.68)	(-6.91, -2.00)	(-9.15, -2.55)	(-10.51, -5.42)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.83	-2.66	-4.01
95% CI of the LS Means Difference		(-5.68, 2.02)	(-7.24, 1.92)	(-8.21, 0.19)
p-value^		0.3383	0.2456	0.0608

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_dciuc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/50
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Previous Number of CIU Medications (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
<=2	17	18	19	19
Change from Baseline in Weekly Itch Severity Score				
n	17	18	19	19
Mean (SD)	-4.50 (4.37)	-6.99 (5.80)	-6.49 (7.01)	-6.81 (5.76)
SE	1.06	1.37	1.61	1.32
Median	-3.5	-6.8	-3.5	-7.0
Range	-13.0 - 0.5	-18.0 - 0.5	-18.5 - 1.5	-18.0 - 0.0
95% CI of the Mean	(-6.74, -2.26)	(-9.87, -4.10)	(-9.87, -3.12)	(-9.58, -4.03)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.84	-1.98	-2.10
95% CI of the LS Means Difference		(-7.40, -0.28)	(-6.05, 2.09)	(-5.75, 1.56)
p-value^		0.0353	0.3286	0.2512
3-5	33	34	40	33
Change from Baseline in Weekly Itch Severity Score				
n	33	34	40	33
Mean (SD)	-2.81 (5.33)	-5.60 (5.58)	-6.29 (6.59)	-10.16 (5.38)
SE	0.93	0.96	1.04	0.94
Median	-0.5	-6.0	-6.3	-10.0
Range	-15.5 - 5.0	-16.0 - 4.0	-21.0 - 5.0	-19.0 - 0.0
95% CI of the Mean	(-4.70, -0.92)	(-7.55, -3.65)	(-8.40, -4.18)	(-12.07, -8.25)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.69	-3.11	-7.39
95% CI of the LS Means Difference		(-5.31, -0.07)	(-5.88, -0.34)	(-10.05, -4.74)
p-value^		0.0441	0.0283	<.0001
>5	30	25	21	29
Change from Baseline in Weekly Itch Severity Score				
n	30	25	21	29

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_pmedc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/50
Subgroup Analysis of Change from Baseline in Weekly Itch Severity Score at Week 12 by Previous Number of CIU Medications (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	-4.05 (5.58)	-7.25 (7.13)	-7.50 (5.07)	-10.23 (5.79)
SE	1.02	1.43	1.11	1.08
Median	-4.5	-5.9	-6.0	-11.0
Range	-18.5 - 7.5	-21.0 - 1.0	-15.5 - 0.0	-19.5 - 0.0
95% CI of the Mean	(-6.13, -1.97)	(-10.19, -4.30)	(-9.81, -5.19)	(-12.43, -8.02)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.40	-4.31	-6.21
95% CI of the LS Means Difference		(-6.75, -0.05)	(-7.20, -1.41)	(-9.11, -3.31)
p-value^		0.0469	0.0045	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval_pmedc)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/19.1
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 12 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Proportion of Itch-Free Days				
n	64	66	64	73
Mean (SD)	18.0% (33.4%)	31.5% (38.4%)	41.7% (42.4%)	54.9% (43.9%)
SE	4.2%	4.7%	5.3%	5.1%
Median	0.0%	0.0%	28.6%	57.1%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(9.7%, 26.3%)	(22.0%, 40.9%)	(31.1%, 52.3%)	(44.6%, 65.1%)
Treatment Difference in LS Means* (relative to the Placebo group)		13.4%	23.9%	38.6%
95% CI of the LS Means Difference		(0.8%, 26.0%)	(10.4%, 37.4%)	(25.1%, 52.0%)
p-value^		0.0373	0.0007	<.0001
Change from Baseline in Proportion of Hive-Free Days				
n	64	66	64	73
Mean (SD)	19.3% (34.7%)	30.6% (37.9%)	42.7% (43.2%)	57.8% (45.4%)
SE	4.3%	4.7%	5.4%	5.3%
Median	0.0%	7.1%	28.6%	80.0%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(10.7%, 28.0%)	(21.2%, 39.9%)	(31.9%, 53.5%)	(47.2%, 68.4%)
Treatment Difference in LS Means* (relative to the Placebo group)		11.1%	24.0%	40.1%
95% CI of the LS Means Difference		(-1.7%, 23.8%)	(10.1%, 37.8%)	(26.2%, 54.1%)
p-value^		0.0876	0.0009	<.0001
Change from Baseline in Proportion of Itch-Free and Hive-Free Days				
n	64	66	64	73
Mean (SD)	17.1% (33.2%)	28.4% (36.9%)	39.8% (41.8%)	51.7% (45.1%)
SE	4.1%	4.5%	5.2%	5.3%

The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 12. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12. This analysis will include only patients who have non-missing weekly itch and hive scores at Week 12. Baseline proportions of itch-free days and /or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (<median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg). ^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_wk12)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/19.1
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 12 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	0.0%	0.0%	14.3%	57.1%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(8.8%, 25.4%)	(19.3%, 37.4%)	(29.4%, 50.3%)	(41.2%, 62.3%)
Treatment Difference in LS Means* (relative to the Placebo group)		11.1%	22.8%	36.1%
95% CI of the LS Means Difference		(-1.2%, 23.4%)	(9.4%, 36.2%)	(22.4%, 49.8%)
p-value^		0.0761	0.0010	<.0001

The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 12. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12. This analysis will include only patients who have non-missing weekly itch and hive scores at Week 12. Baseline proportions of itch-free days and /or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (<median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg). ^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_wk12)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/30
Time (Weeks) to Minimally Important Difference (MID) Response in UAS7 up to Week 12
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of patients	80	77	80	81
Number of patients with an event (%)	50 (62.5%)	56 (72.7%)	62 (77.5%)	73 (90.1%)
Number of patients without an event (%)	30 (37.5%)	21 (27.3%)	18 (22.5%)	8 (9.9%)
Time to MID response (weeks)				
Median	6.0	3.0	3.0	1.5
(95% CI)	(3.0, 9.0)	(2.0, 5.0)	(2.0, 6.0)	(1.0, 2.0)
25th - 75th percentile	2.0 - NE	1.0 - 10.0	1.0 - 9.0	1.0 - 4.5
Minimum - Maximum	1.0 - 12.0+	0.0+ - 12.0+	1.0 - 12.0+	0.0+ - 12.0+
Stratified analysis				
Hazard ratio (relative to the Placebo group)		1.52	1.67	2.69
(95% CI)		(1.03 , 2.24)	(1.15 , 2.44)	(1.86 , 3.90)
p-value		0.0352	0.0077	<.0001

+ = censored value.
Summaries of time to event variable (median, percentiles, and range) are based on Kaplan-Meier estimates of the distribution of the time to a reduction from baseline in UAS7 of >= 11 points (MID response) by week 12.
The 95% confidence interval (CI) for the median was computed using the method of Brookmeyer and Crowley. Hazard ratios are estimated using Cox proportional hazards (PH) models stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg). Separate models were run for each omalizumab dose compared to placebo.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_mid_tte)
Database (CLOSED) Datasets (pat pateff diaryeff)
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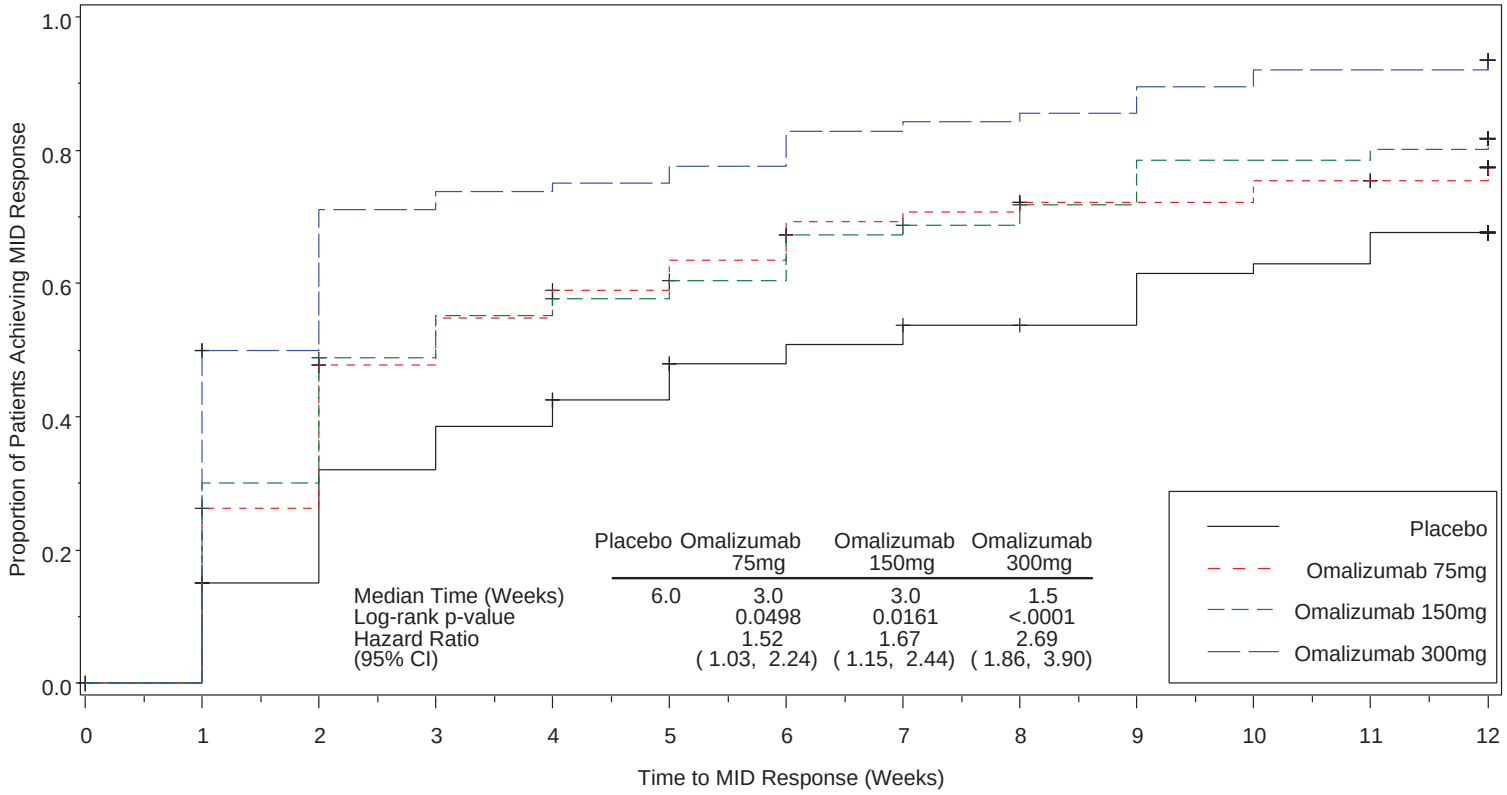
Figure 14.2/5
Time to Minimally Important Difference (MID) Response in UAS7 by Week 12
Modified Intention to Treat Patients



Number of Patients at risk

Placebo	80	80	65	52	47	42	36	34	31	30	25	24	21
Omalizumab 75mg	77	76	55	37	32	28	25	21	20	17	17	15	13
Omalizumab 150mg	80	80	56	40	35	32	29	22	20	17	13	13	12
Omalizumab 300mg	81	80	38	22	20	19	17	13	12	11	8	6	6

Source: Biostatistics[redacted] pgm(/allergy/E25/q4881g/final/programs/g_mid_tte) output (g_uas_mid_tte)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/20.1
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Proportion of Itch-Free Days				
n	80	77	80	81
Mean (SD)	14.4% (30.7%)	27.0% (37.2%)	33.3% (41.4%)	49.5% (44.8%)
SE	3.4%	4.2%	4.6%	5.0%
Median	0.0%	0.0%	0.0%	57.1%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(7.6%, 21.2%)	(18.5%, 35.4%)	(24.1%, 42.6%)	(39.6%, 59.4%)
Treatment Difference in LS Means* (relative to the Placebo group)		12.5%	18.8%	35.7%
95% CI of the LS Means Difference		(1.7%, 23.3%)	(7.3%, 30.2%)	(23.7%, 47.8%)
p-value^		0.0231	0.0014	<.0001
Change from Baseline in Proportion of Hive-Free Days				
n	80	77	80	81
Mean (SD)	15.5% (32.0%)	26.2% (36.7%)	34.2% (42.3%)	52.1% (46.4%)
SE	3.6%	4.2%	4.7%	5.2%
Median	0.0%	0.0%	0.0%	57.1%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(8.4%, 22.6%)	(17.9%, 34.5%)	(24.8%, 43.6%)	(41.8%, 62.3%)
Treatment Difference in LS Means* (relative to the Placebo group)		10.6%	18.7%	37.2%
95% CI of the LS Means Difference		(-0.3%, 21.5%)	(6.9%, 30.4%)	(24.7%, 49.7%)
p-value^		0.0555	0.0020	<.0001
Change from Baseline in Proportion of Itch-Free and Hive-Free Days				
n	80	77	80	81
Mean (SD)	13.7% (30.4%)	24.3% (35.5%)	31.9% (40.6%)	46.6% (45.6%)
SE	3.4%	4.1%	4.5%	5.1%

BOCF = Baseline observation carried forward. The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number of days in Week 12. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12. Baseline proportions of itch-free days and/or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date. * The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_bocf_wk12)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/20.1
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	0.0%	0.0%	0.0%	28.6%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(6.9%, 20.5%)	(16.2%, 32.4%)	(22.8%, 40.9%)	(36.6%, 56.7%)
Treatment Difference in LS Means* (relative to the Placebo group)		10.5%	18.0%	33.5%
95% CI of the LS Means Difference		(0.1%, 21.0%)	(6.7%, 29.2%)	(21.3%, 45.7%)
p-value^		0.0486	0.0019	<.0001

BOCF = Baseline observation carried forward. The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number of days in Week 12. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 12. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 12. Baseline proportions of itch-free days and/or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date. * The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_bocf_wk12)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/22
Change from Baseline in Weekly Sleep Interference Score at Week 12 and Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Sleep Interference Score at Week 12				
n	80	77	80	81
Mean (SD)	-3.86 (5.07)	-5.85 (5.78)	-5.63 (6.09)	-8.67 (5.80)
SE	0.57	0.66	0.68	0.64
Median	-2.2	-6.0	-4.5	-9.5
Range	-18.0 - 6.0	-18.0 - 1.0	-21.0 - 5.0	-20.0 - 4.0
95% CI of the Mean	(-4.99, -2.73)	(-7.16, -4.53)	(-6.98, -4.27)	(-9.95, -7.39)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.82	-1.70	-4.78
95% CI of the LS Means Difference		(-3.51, -0.13)	(-3.42, 0.02)	(-6.45, -3.10)
p-value^		0.0345	0.0532	<.0001
Change from Baseline in Weekly Sleep Interference Score at Week 24				
n	80	77	80	81
Mean (SD)	-4.89 (5.47)	-6.13 (6.32)	-5.64 (6.54)	-8.49 (6.01)
SE	0.61	0.72	0.73	0.67
Median	-4.0	-7.0	-3.6	-10.0
Range	-21.0 - 6.0	-21.0 - 6.0	-21.0 - 4.0	-20.0 - 2.3
95% CI of the Mean	(-6.11, -3.67)	(-7.57, -4.70)	(-7.09, -4.18)	(-9.82, -7.16)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.06	-0.69	-3.61
95% CI of the LS Means Difference		(-2.89, 0.76)	(-2.53, 1.15)	(-5.40, -1.82)
p-value^		0.2518	0.4587	0.0001

Baseline weekly sleep interference score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline weekly sleep interference score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_sleep_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/23
Change from Baseline in Weekly Interference with Daily Activities Score at Week 12 and Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Interference with Daily Activities Score at Week 12				
n	80	77	80	81
Mean (SD)	-3.82 (5.53)	-5.98 (6.16)	-6.35 (6.35)	-9.15 (5.63)
SE	0.62	0.70	0.71	0.63
Median	-2.7	-5.0	-5.5	-10.0
Range	-19.0 - 8.0	-19.0 - 4.4	-21.0 - 5.0	-20.0 - 3.4
95% CI of the Mean	(-5.05, -2.59)	(-7.37, -4.58)	(-7.76, -4.94)	(-10.40, -7.91)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.10	-2.54	-5.39
95% CI of the LS Means Difference		(-3.92, -0.29)	(-4.37, -0.72)	(-7.12, -3.67)
p-value^		0.0230	0.0067	<.0001
Change from Baseline in Weekly Interference with Daily Activities Score at Week 24				
n	80	77	80	81
Mean (SD)	-5.18 (6.01)	-6.61 (6.34)	-6.18 (6.88)	-9.21 (5.96)
SE	0.67	0.72	0.77	0.66
Median	-4.0	-7.4	-5.0	-9.0
Range	-21.0 - 4.0	-21.0 - 7.0	-21.0 - 6.3	-20.0 - 2.0
95% CI of the Mean	(-6.52, -3.85)	(-8.05, -5.17)	(-7.71, -4.65)	(-10.53, -7.89)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.34	-1.03	-4.09
95% CI of the LS Means Difference		(-3.24, 0.56)	(-2.95, 0.90)	(-5.94, -2.24)
p-value^		0.1644	0.2925	<.0001

Baseline weekly interference with daily activities score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline weekly interference with daily activities score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_activity_lsmpval)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/21
Change from Baseline in Rescue Medication Use (Tablets/Week of Diphenhydramine (25 mg)) at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Rescue Medication Use (Tablets/Week of Diphenhydramine (25 mg))				
n	80	77	80	81
Mean (SD)	-1.00 (5.22)	-2.29 (6.85)	-2.94 (7.07)	-4.20 (6.35)
SE	0.58	0.78	0.79	0.71
Median	0.0	0.0	0.0	-1.0
Range	-20.0 - 9.0	-21.0 - 15.0	-45.0 - 6.0	-22.0 - 5.8
95% CI of the Mean	(-2.17, 0.16)	(-3.84, -0.73)	(-4.51, -1.36)	(-5.60, -2.80)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.42	-2.16	-3.39
95% CI of the LS Means Difference		(-3.29, 0.45)	(-4.04, -0.28)	(-5.07, -1.70)
p-value^		0.1356	0.0249	0.0001

BOCF = Baseline observation carried forward.
Baseline number of tablets/week is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline number of tablets/week (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_sedating_lsmpval)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/17.1

Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Overall Score at Week 12, Week 24 and Week 40 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in CU-Q2oL Overall Score at Week 12				
n	49	50	48	57
Mean (SD)	-19.7 (19.7)	-19.2 (19.0)	-23.1 (18.6)	-30.5 (19.1)
SE	2.8	2.7	2.7	2.5
Median	-19.6	-18.5	-22.8	-29.3
Range	-76.1 - 21.7	-64.1 - 20.7	-85.9 - 13.0	-84.8 - 4.3
95% CI of the Mean	(-25.3, -14.0)	(-24.6, -13.8)	(-28.5, -17.7)	(-35.6, -25.5)
Treatment Difference in LS Means* (relative to the Placebo group)		-0.0	-3.9	-10.6
95% CI of the LS Means Difference		(-7.1, 7.1)	(-11.2, 3.4)	(-17.2, -4.0)
p-value^		0.9916	0.2891	0.0019
Change from Baseline in CU-Q2oL Overall Score at Week 24				
n	42	45	43	55
Mean (SD)	-25.4 (18.3)	-21.8 (20.0)	-23.8 (20.6)	-33.0 (19.8)
SE	2.8	3.0	3.1	2.7
Median	-24.5	-20.7	-23.9	-32.6
Range	-66.3 - 8.5	-66.3 - 33.7	-79.3 - 22.8	-78.3 - 0.0
95% CI of the Mean	(-31.1, -19.7)	(-27.8, -15.8)	(-30.1, -17.4)	(-38.3, -27.6)
Treatment Difference in LS Means* (relative to the Placebo group)		3.3	1.5	-6.7
95% CI of the LS Means Difference		(-3.8, 10.5)	(-6.1, 9.2)	(-13.3, -0.2)
p-value^		0.3577	0.6952	0.0443
Change from Baseline in CU-Q2oL Overall Score at Week 40				
n	36	34	38	38
Mean (SD)	-25.2 (23.8)	-20.7 (16.7)	-14.2 (19.3)	-17.8 (24.2)
SE	4.0	2.9	3.1	3.9

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline CU-Q2oL overall and domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.
*The LS mean was estimated using ANCOVA model. The strata are for baseline overall score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqolwks)
Database (CLOSED) Datasets (cuqeff pat)
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Table 14.2/17.1

Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Overall Score at Week 12, Week 24 and Week 40 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	-25.0	-18.5	-10.3	-17.9
Range	-83.7 - 26.1	-69.6 - 1.1	-67.4 - 27.2	-60.9 - 50.0
95% CI of the Mean	(-33.2, -17.1)	(-26.6, -14.9)	(-20.6, -7.9)	(-25.8, -9.9)
Treatment Difference in LS Means* (relative to the Placebo group)		3.3	10.6	8.6
95% CI of the LS Means Difference		(-5.8, 12.4)	(1.6, 19.6)	(-1.7, 18.9)
p-value^		0.4676	0.0216	0.0986

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline CU-Q2oL overall and domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.
*The LS mean was estimated using ANCOVA model. The strata are for baseline overall score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqolwks)
Database (CLOSED) Datasets (cuqeff pat)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Overall

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	46.0	18.4	45.7	15.2	83.7	46.0	18.4	45.7	15.2	83.7					
Omalizumab 75mg	59	43.8	17.6	41.3	13.0	87.0	43.8	17.6	41.3	13.0	87.0					
Omalizumab 150mg	63	44.4	20.8	44.6	7.6	93.5	44.4	20.8	44.6	7.6	93.5					
Omalizumab 300mg	61	44.1	18.2	44.6	13.0	84.8	44.1	18.2	44.6	13.0	84.8					
Week 4																
Placebo	57	46.1	18.4	45.7	15.2	83.7	31.9	19.9	29.3	5.4	88.0	-14.2	19.0	-10.9	-70.7	15.2
Omalizumab 75mg	55	44.2	17.4	41.3	15.2	87.0	33.9	19.4	32.6	3.3	84.8	-10.4	14.4	-10.9	-46.7	18.5
Omalizumab 150mg	61	44.7	21.1	45.7	7.6	93.5	30.3	24.4	26.1	0.0	95.7	-14.4	18.5	-12.3	-84.8	21.7
Omalizumab 300mg	59	44.4	18.3	44.6	13.0	84.8	21.0	18.1	16.3	0.0	65.2	-23.3	19.3	-21.7	-84.8	10.9
Week 12																
Placebo	49	43.9	17.4	44.6	17.4	83.7	24.3	18.4	20.7	0.0	68.5	-19.7	19.7	-19.6	-76.1	21.7
Omalizumab 75mg	50	44.6	16.9	42.4	13.0	87.0	25.4	19.7	23.9	0.0	76.1	-19.2	19.0	-18.5	-64.1	20.7
Omalizumab 150mg	48	44.1	21.5	43.5	7.6	93.5	21.0	21.0	13.0	0.0	71.7	-23.1	18.6	-22.8	-85.9	13.0
Omalizumab 300mg	57	44.6	18.4	44.6	13.0	84.8	14.1	14.3	9.8	0.0	48.9	-30.5	19.1	-29.3	-84.8	4.3
Week 24																
Placebo	42	43.8	17.9	43.5	15.2	83.7	18.4	15.2	12.0	0.0	60.7	-25.4	18.3	-24.5	-66.3	8.5
Omalizumab 75mg	45	44.6	17.4	41.3	13.0	87.0	22.8	21.5	16.3	0.0	75.0	-21.8	20.0	-20.7	-66.3	33.7
Omalizumab 150mg	43	43.7	21.9	43.5	7.6	93.5	19.9	23.3	10.9	0.0	84.8	-23.8	20.6	-23.9	-79.3	22.8
Omalizumab 300mg	55	44.6	18.3	44.6	13.0	84.8	11.6	12.8	6.5	0.0	50.0	-33.0	19.8	-32.6	-78.3	0.0
Week 40																
Placebo	36	43.0	17.5	43.5	15.2	83.7	17.8	18.9	10.9	0.0	75.0	-25.2	23.8	-25.0	-83.7	26.1
Omalizumab 75mg	34	43.3	18.1	41.3	13.0	87.0	22.6	20.4	17.4	0.0	81.5	-20.7	16.7	-18.5	-69.6	1.1
Omalizumab 150mg	38	43.1	22.4	44.6	7.6	93.5	28.9	23.5	24.5	0.0	84.8	-14.2	19.3	-10.3	-67.4	27.2
Omalizumab 300mg	38	44.8	18.8	46.7	13.0	79.3	27.0	20.8	23.4	0.0	64.1	-17.8	24.2	-17.9	-60.9	50.0
Early Term																
Placebo	1	47.8		47.8	47.8	47.8	44.3		44.3	44.3	44.3	-3.5		-3.5	-3.5	-3.5
Omalizumab 75mg	1	47.8		47.8	47.8	47.8	68.5		68.5	68.5	68.5	20.7		20.7	20.7	20.7
Omalizumab 150mg	4	48.9	19.5	47.3	28.3	72.8	39.4	26.1	48.4	1.1	59.8	-9.5	36.0	-2.2	-54.3	20.7

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Overall

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	34.1	15.3	32.6	19.6	50.0	44.9	40.4	26.1	17.4	91.3	10.9	28.5	6.5	-15.2	41.3

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Pruritus

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	79.4	19.3	75.0	25.0	100.0	79.4	19.3	75.0	25.0	100.0					
Omalizumab 75mg	59	78.6	18.6	75.0	50.0	100.0	78.6	18.6	75.0	50.0	100.0					
Omalizumab 150mg	63	76.6	20.6	75.0	25.0	100.0	76.6	20.6	75.0	25.0	100.0					
Omalizumab 300mg	61	79.5	17.8	75.0	25.0	100.0	79.5	17.8	75.0	25.0	100.0					
Week 4																
Placebo	57	78.1	19.7	75.0	25.0	100.0	56.1	26.2	62.5	0.0	100.0	-21.9	27.1	-25.0	-87.5	25.0
Omalizumab 75mg	55	78.4	18.9	75.0	50.0	100.0	62.0	28.5	75.0	0.0	100.0	-16.4	27.1	-12.5	-75.0	37.5
Omalizumab 150mg	61	76.2	20.8	75.0	25.0	100.0	50.8	32.8	50.0	0.0	100.0	-25.4	30.7	-25.0	-100.0	37.5
Omalizumab 300mg	59	79.2	17.9	75.0	25.0	100.0	38.8	29.9	37.5	0.0	100.0	-40.5	31.7	-37.5	-100.0	25.0
Week 12																
Placebo	49	77.8	19.0	75.0	37.5	100.0	49.7	28.2	50.0	0.0	100.0	-28.1	29.5	-25.0	-100.0	50.0
Omalizumab 75mg	50	79.3	18.0	75.0	50.0	100.0	48.5	31.2	50.0	0.0	100.0	-30.8	32.5	-25.0	-100.0	37.5
Omalizumab 150mg	48	74.2	20.2	75.0	25.0	100.0	33.6	28.4	25.0	0.0	100.0	-40.6	27.1	-43.8	-100.0	12.5
Omalizumab 300mg	57	80.0	17.7	75.0	25.0	100.0	23.2	24.9	25.0	0.0	100.0	-56.8	30.4	-62.5	-100.0	25.0
Week 24																
Placebo	42	77.4	20.0	75.0	25.0	100.0	38.1	27.0	37.5	0.0	100.0	-39.3	25.2	-37.5	-75.0	25.0
Omalizumab 75mg	44	79.3	18.7	75.0	50.0	100.0	40.1	32.2	25.0	0.0	100.0	-39.2	29.2	-50.0	-100.0	12.5
Omalizumab 150mg	43	74.7	20.9	75.0	25.0	100.0	34.0	30.5	25.0	0.0	100.0	-40.7	26.7	-37.5	-100.0	12.5
Omalizumab 300mg	55	79.8	17.8	75.0	25.0	100.0	18.6	23.8	12.5	0.0	100.0	-61.1	29.6	-75.0	-100.0	12.5
Week 40																
Placebo	36	76.7	19.9	75.0	25.0	100.0	39.2	30.1	37.5	0.0	100.0	-37.5	35.4	-43.8	-100.0	37.5
Omalizumab 75mg	34	78.7	19.3	75.0	50.0	100.0	43.8	26.0	50.0	0.0	100.0	-34.9	27.7	-37.5	-87.5	0.0
Omalizumab 150mg	38	73.4	21.2	75.0	25.0	100.0	49.0	30.4	50.0	0.0	100.0	-24.3	27.6	-25.0	-100.0	25.0
Omalizumab 300mg	38	76.6	17.7	75.0	25.0	100.0	51.3	33.7	56.3	0.0	100.0	-25.3	38.2	-25.0	-100.0	50.0
Early Term																
Placebo	1	50.0		50.0	50.0	50.0	100.0		100.0	100.0	100.0	50.0		50.0	50.0	50.0
Omalizumab 75mg	1	100.0		100.0	100.0	100.0	100.0		100.0	100.0	100.0	0.0		0.0	0.0	0.0
Omalizumab 150mg	4	75.0	10.2	75.0	62.5	87.5	68.8	46.2	87.5	0.0	100.0	-6.3	46.2	12.5	-75.0	25.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Pruritus

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	79.2	19.1	75.0	62.5	100.0	75.0	21.7	62.5	62.5	100.0	-4.2	7.2	0.0	-12.5	0.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Swelling

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	28.6	27.1	25.0	0.0	100.0	28.6	27.1	25.0	0.0	100.0					
Omalizumab 75mg	59	22.5	26.2	12.5	0.0	87.5	22.5	26.2	12.5	0.0	87.5					
Omalizumab 150mg	63	23.8	28.5	12.5	0.0	100.0	23.8	28.5	12.5	0.0	100.0					
Omalizumab 300mg	61	21.9	26.1	12.5	0.0	100.0	21.9	26.1	12.5	0.0	100.0					
Week 4																
Placebo	57	28.3	27.2	25.0	0.0	100.0	19.3	22.2	12.5	0.0	75.0	-9.0	24.2	0.0	-75.0	50.0
Omalizumab 75mg	55	22.3	25.9	12.5	0.0	87.5	18.6	27.1	0.0	0.0	100.0	-3.6	17.3	0.0	-37.5	50.0
Omalizumab 150mg	61	23.2	27.6	12.5	0.0	100.0	15.2	23.8	0.0	0.0	100.0	-8.0	20.4	0.0	-87.5	37.5
Omalizumab 300mg	59	22.7	26.2	12.5	0.0	100.0	9.5	16.8	0.0	0.0	75.0	-13.1	23.1	-12.5	-75.0	37.5
Week 12																
Placebo	49	25.8	27.4	12.5	0.0	100.0	15.1	19.9	12.5	0.0	75.0	-10.7	28.3	0.0	-87.5	62.5
Omalizumab 75mg	49	21.4	25.5	12.5	0.0	87.5	14.3	24.6	0.0	0.0	100.0	-7.1	23.8	0.0	-62.5	62.5
Omalizumab 150mg	48	19.8	24.3	12.5	0.0	87.5	8.6	20.0	0.0	0.0	87.5	-11.2	20.3	0.0	-75.0	37.5
Omalizumab 300mg	57	23.0	26.5	12.5	0.0	100.0	6.4	13.2	0.0	0.0	50.0	-16.7	24.6	-12.5	-100.0	25.0
Week 24																
Placebo	42	24.7	27.0	18.8	0.0	100.0	7.7	13.2	0.0	0.0	50.0	-17.0	25.7	-12.5	-100.0	25.0
Omalizumab 75mg	45	21.1	26.5	12.5	0.0	87.5	13.3	25.1	0.0	0.0	100.0	-7.8	23.9	0.0	-87.5	50.0
Omalizumab 150mg	43	19.5	25.3	12.5	0.0	87.5	8.1	23.0	0.0	0.0	100.0	-11.3	20.4	0.0	-62.5	25.0
Omalizumab 300mg	55	22.3	26.0	12.5	0.0	100.0	4.5	11.1	0.0	0.0	62.5	-17.7	26.5	-12.5	-87.5	37.5
Week 40																
Placebo	36	23.3	25.4	18.8	0.0	100.0	8.3	22.4	0.0	0.0	100.0	-14.9	28.6	-12.5	-100.0	50.0
Omalizumab 75mg	34	19.1	23.1	12.5	0.0	75.0	11.8	22.0	0.0	0.0	100.0	-7.4	19.0	0.0	-62.5	37.5
Omalizumab 150mg	38	19.7	26.1	6.3	0.0	87.5	10.9	19.7	0.0	0.0	75.0	-8.9	21.3	0.0	-87.5	25.0
Omalizumab 300mg	38	25.0	27.6	12.5	0.0	100.0	13.5	24.2	0.0	0.0	100.0	-11.5	31.4	-12.5	-75.0	75.0
Early Term																
Omalizumab 75mg	1	0.0		0.0	0.0	0.0	37.5		37.5	37.5	37.5	37.5		37.5	37.5	37.5
Omalizumab 150mg	4	37.5	10.2	37.5	25.0	50.0	37.5	43.3	37.5	0.0	75.0	0.0	44.5	-6.3	-37.5	50.0
Omalizumab 300mg	3	29.2	28.9	12.5	12.5	62.5	45.8	47.3	25.0	12.5	100.0	16.7	64.1	0.0	-37.5	87.5

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Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Impact on Life Activities

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	45.1	23.5	50.0	0.0	87.5	45.1	23.5	50.0	0.0	87.5					
Omalizumab 75mg	59	41.9	22.8	41.7	0.0	100.0	41.9	22.8	41.7	0.0	100.0					
Omalizumab 150mg	63	43.0	24.4	45.8	4.2	100.0	43.0	24.4	45.8	4.2	100.0					
Omalizumab 300mg	61	43.7	21.7	50.0	4.2	79.2	43.7	21.7	50.0	4.2	79.2					
Week 4																
Placebo	57	44.3	22.6	45.8	4.2	87.5	28.0	22.8	25.0	0.0	91.7	-16.4	25.1	-8.3	-87.5	41.7
Omalizumab 75mg	55	42.4	22.5	41.7	4.2	100.0	33.1	23.6	33.3	0.0	95.8	-9.3	20.2	-12.5	-50.0	37.5
Omalizumab 150mg	61	43.2	24.7	45.8	4.2	100.0	27.7	27.0	20.8	0.0	95.8	-15.5	24.1	-12.5	-95.8	41.7
Omalizumab 300mg	59	43.8	22.0	50.0	4.2	79.2	17.1	18.3	12.5	0.0	66.7	-26.7	22.5	-20.8	-75.0	8.3
Week 12																
Placebo	49	42.6	22.2	41.7	4.2	87.5	19.0	18.2	12.5	0.0	75.0	-23.6	25.3	-20.8	-87.5	29.2
Omalizumab 75mg	50	41.9	22.2	41.7	0.0	100.0	22.2	22.5	18.8	0.0	79.2	-19.8	24.4	-20.8	-75.0	50.0
Omalizumab 150mg	48	43.8	25.8	45.8	4.2	100.0	16.1	20.9	8.3	0.0	75.0	-27.7	23.0	-25.0	-95.8	4.2
Omalizumab 300mg	57	44.2	22.0	50.0	4.2	79.2	9.6	14.7	0.0	0.0	50.0	-34.7	23.6	-33.3	-79.2	12.5
Week 24																
Placebo	42	41.9	21.4	41.7	4.2	87.5	12.8	13.9	8.3	0.0	50.0	-29.1	22.5	-25.0	-75.0	0.0
Omalizumab 75mg	45	42.6	22.5	41.7	0.0	100.0	19.1	23.7	8.3	0.0	83.3	-23.5	25.6	-25.0	-75.0	45.8
Omalizumab 150mg	43	43.6	26.2	45.8	4.2	100.0	16.6	24.8	4.2	0.0	91.7	-27.0	25.0	-20.8	-95.8	33.3
Omalizumab 300mg	55	44.4	21.9	50.0	4.2	79.2	7.3	12.8	0.0	0.0	50.0	-37.1	23.0	-37.5	-79.2	0.0
Week 40																
Placebo	36	41.2	21.7	41.7	4.2	87.5	15.9	22.2	4.2	0.0	75.0	-25.3	30.7	-25.0	-87.5	41.7
Omalizumab 75mg	34	41.9	21.6	41.7	0.0	100.0	17.8	21.6	10.4	0.0	87.5	-24.1	19.8	-20.8	-70.8	12.5
Omalizumab 150mg	38	42.2	26.7	41.7	4.2	100.0	27.2	27.6	18.8	0.0	100.0	-15.0	24.6	-12.5	-75.0	41.7
Omalizumab 300mg	38	42.2	22.3	43.8	4.2	75.0	22.9	22.5	14.6	0.0	70.8	-19.3	28.4	-20.8	-70.8	50.0
Early Term																
Placebo	1	62.5		62.5	62.5	62.5	54.2		54.2	54.2	54.2	-8.3		-8.3	-8.3	-8.3
Omalizumab 75mg	1	25.0		25.0	25.0	25.0	75.0		75.0	75.0	75.0	50.0		50.0	50.0	50.0
Omalizumab 150mg	4	49.0	21.3	52.1	20.8	70.8	34.4	27.3	35.4	0.0	66.7	-14.6	39.5	-10.4	-58.3	20.8

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2

Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Impact on Life Activities

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	36.1	17.3	41.7	16.7	50.0	40.3	34.7	29.2	12.5	79.2	4.2	30.0	12.5	-29.2	29.2

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Sleep Problems

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	48.7	23.6	45.0	0.0	100.0	48.7	23.6	45.0	0.0	100.0					
Omalizumab 75mg	59	46.8	22.7	50.0	10.0	95.0	46.8	22.7	50.0	10.0	95.0					
Omalizumab 150mg	63	48.2	25.2	45.0	5.0	100.0	48.2	25.2	45.0	5.0	100.0					
Omalizumab 300mg	61	49.3	22.9	50.0	10.0	95.0	49.3	22.9	50.0	10.0	95.0					
Week 4																
Placebo	57	48.5	23.3	45.0	0.0	100.0	34.6	23.6	30.0	5.0	100.0	-13.9	23.3	-10.0	-95.0	20.0
Omalizumab 75mg	55	47.5	22.7	50.0	10.0	95.0	35.6	22.2	35.0	0.0	90.0	-11.8	18.0	-10.0	-55.0	30.0
Omalizumab 150mg	60	49.0	25.6	45.0	5.0	100.0	35.7	27.1	30.0	0.0	100.0	-13.3	21.0	-10.0	-95.0	30.0
Omalizumab 300mg	59	49.7	22.7	50.0	10.0	95.0	25.3	22.4	25.0	0.0	80.0	-24.3	23.6	-20.0	-95.0	20.0
Week 12																
Placebo	49	46.0	21.8	45.0	0.0	100.0	27.2	23.5	20.0	0.0	85.0	-18.8	23.5	-15.0	-95.0	30.0
Omalizumab 75mg	50	47.8	22.2	50.0	10.0	95.0	27.3	21.6	25.0	0.0	75.0	-20.5	21.6	-20.0	-75.0	30.0
Omalizumab 150mg	48	48.6	25.6	45.0	10.0	100.0	26.6	25.0	22.5	0.0	90.0	-22.1	25.4	-15.0	-100.0	40.0
Omalizumab 300mg	57	49.6	22.9	50.0	10.0	95.0	19.5	18.0	15.0	0.0	65.0	-30.2	23.8	-30.0	-95.0	10.0
Week 24																
Placebo	42	45.7	23.1	45.0	0.0	100.0	23.2	19.5	17.5	0.0	85.0	-22.5	24.4	-20.0	-85.0	15.0
Omalizumab 75mg	45	49.1	22.2	50.0	10.0	95.0	24.7	22.0	20.0	0.0	75.0	-24.4	26.5	-25.0	-75.0	45.0
Omalizumab 150mg	43	47.9	25.8	45.0	10.0	100.0	25.1	25.9	15.0	0.0	85.0	-22.8	29.0	-15.0	-100.0	45.0
Omalizumab 300mg	55	49.9	22.9	50.0	10.0	95.0	16.5	18.0	15.0	0.0	70.0	-33.5	25.7	-35.0	-90.0	20.0
Week 40																
Placebo	36	44.2	22.6	45.0	0.0	100.0	19.6	23.0	12.5	0.0	80.0	-24.6	27.2	-27.5	-100.0	50.0
Omalizumab 75mg	34	50.3	23.9	50.0	10.0	95.0	24.7	23.3	20.0	0.0	100.0	-25.6	23.9	-20.0	-90.0	15.0
Omalizumab 150mg	38	49.1	26.0	45.0	10.0	100.0	34.2	28.0	25.0	0.0	100.0	-14.9	27.7	-12.5	-85.0	50.0
Omalizumab 300mg	38	52.1	22.7	50.0	10.0	95.0	29.1	24.0	25.0	0.0	75.0	-23.0	25.1	-25.0	-75.0	45.0
Early Term																
Placebo	1	35.0		35.0	35.0	35.0	15.0		15.0	15.0	15.0	-20.0		-20.0	-20.0	-20.0
Omalizumab 75mg	1	60.0		60.0	60.0	60.0	55.0		55.0	55.0	55.0	-5.0		-5.0	-5.0	-5.0
Omalizumab 150mg	4	41.3	33.3	30.0	15.0	90.0	45.0	30.3	50.0	5.0	75.0	3.8	27.8	5.0	-25.0	30.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2

Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Sleep Problems

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	30.0	18.0	25.0	15.0	50.0	46.7	46.2	20.0	20.0	100.0	16.7	29.3	5.0	-5.0	50.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

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Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Limits

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	37.6	25.4	33.3	0.0	83.3	37.6	25.4	33.3	0.0	83.3					
Omalizumab 75mg	59	32.5	23.7	25.0	0.0	91.7	32.5	23.7	25.0	0.0	91.7					
Omalizumab 150mg	63	36.1	26.7	33.3	0.0	100.0	36.1	26.7	33.3	0.0	100.0					
Omalizumab 300mg	61	30.7	24.3	25.0	0.0	91.7	30.7	24.3	25.0	0.0	91.7					
Week 4																
Placebo	57	38.7	24.9	33.3	0.0	83.3	25.9	23.0	16.7	0.0	100.0	-12.9	20.3	-8.3	-66.7	16.7
Omalizumab 75mg	55	32.4	23.9	25.0	0.0	91.7	25.9	22.4	25.0	0.0	83.3	-6.5	16.3	-8.3	-41.7	33.3
Omalizumab 150mg	60	36.8	27.0	33.3	0.0	100.0	26.3	27.4	16.7	0.0	91.7	-10.5	20.8	-8.3	-100.0	29.2
Omalizumab 300mg	59	31.4	24.4	25.0	0.0	91.7	16.2	20.0	8.3	0.0	66.7	-15.1	21.2	-8.3	-83.3	25.0
Week 12																
Placebo	49	35.9	24.5	33.3	0.0	83.3	17.9	19.9	16.7	0.0	83.3	-17.9	20.8	-16.7	-83.3	25.0
Omalizumab 75mg	50	34.2	24.3	29.2	0.0	91.7	18.2	21.3	8.3	0.0	75.0	-16.0	22.6	-8.3	-66.7	33.3
Omalizumab 150mg	48	35.4	26.0	33.3	0.0	100.0	19.6	24.1	12.5	0.0	100.0	-15.8	21.5	-8.3	-100.0	25.0
Omalizumab 300mg	57	31.6	24.6	25.0	0.0	91.7	11.7	18.2	0.0	0.0	75.0	-19.9	23.3	-16.7	-83.3	25.0
Week 24																
Placebo	42	35.3	24.8	33.3	0.0	83.3	14.2	16.8	8.3	0.0	75.0	-21.1	21.9	-16.7	-58.3	25.0
Omalizumab 75mg	45	33.9	25.0	25.0	0.0	91.7	19.8	23.7	8.3	0.0	66.7	-14.1	22.4	-16.7	-66.7	50.0
Omalizumab 150mg	43	34.9	26.7	33.3	0.0	100.0	17.8	24.4	8.3	0.0	83.3	-17.1	23.9	-8.3	-100.0	33.3
Omalizumab 300mg	55	31.5	24.9	25.0	0.0	91.7	9.8	15.5	0.0	0.0	66.7	-21.7	23.9	-16.7	-83.3	16.7
Week 40																
Placebo	36	35.2	25.5	33.3	0.0	83.3	12.3	15.9	4.2	0.0	50.0	-22.9	27.0	-25.0	-83.3	41.7
Omalizumab 75mg	34	30.4	26.7	25.0	0.0	91.7	16.4	21.8	8.3	0.0	75.0	-14.0	19.8	-8.3	-75.0	16.7
Omalizumab 150mg	38	34.4	27.5	29.2	0.0	100.0	22.6	26.4	12.5	0.0	83.3	-11.8	18.8	-8.3	-58.3	41.7
Omalizumab 300mg	38	32.5	23.6	25.0	0.0	91.7	19.7	22.5	16.7	0.0	91.7	-12.7	23.5	-12.5	-58.3	41.7
Early Term																
Placebo	1	66.7		66.7	66.7	66.7	41.7		41.7	41.7	41.7	-25.0		-25.0	-25.0	-25.0
Omalizumab 75mg	1	33.3		33.3	33.3	33.3	58.3		58.3	58.3	58.3	25.0		25.0	25.0	25.0
Omalizumab 150mg	4	47.9	24.9	41.7	25.0	83.3	31.3	24.9	33.3	0.0	58.3	-16.7	47.1	-0.0	-83.3	16.7

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Limits

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	13.9	17.3	8.3	0.0	33.3	38.9	39.4	25.0	8.3	83.3	25.0	25.0	25.0	0.0	50.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

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Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2
Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Looks

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	63	43.3	22.5	45.0	0.0	85.0	43.3	22.5	45.0	0.0	85.0					
Omalizumab 75mg	59	44.2	24.1	45.0	0.0	85.0	44.2	24.1	45.0	0.0	85.0					
Omalizumab 150mg	63	42.5	25.6	40.0	0.0	100.0	42.5	25.6	40.0	0.0	100.0					
Omalizumab 300mg	61	42.4	21.9	45.0	0.0	95.0	42.4	21.9	45.0	0.0	95.0					
Week 4																
Placebo	57	44.4	23.2	45.0	0.0	85.0	32.9	24.3	30.0	0.0	90.0	-11.5	17.6	-5.0	-60.0	15.0
Omalizumab 75mg	55	45.4	24.4	45.0	0.0	85.0	32.5	25.3	30.0	0.0	90.0	-12.8	17.9	-15.0	-70.0	20.0
Omalizumab 150mg	61	43.1	25.7	45.0	0.0	100.0	28.3	27.8	20.0	0.0	95.0	-14.8	19.8	-12.5	-80.0	45.0
Omalizumab 300mg	59	42.3	22.2	45.0	0.0	95.0	21.8	20.9	20.0	0.0	90.0	-20.5	22.1	-20.0	-95.0	30.0
Week 12																
Placebo	48	41.4	22.2	42.5	0.0	80.0	24.8	23.3	17.5	0.0	85.0	-16.6	22.1	-20.0	-70.0	25.0
Omalizumab 75mg	50	46.6	23.9	50.0	0.0	85.0	27.1	23.8	25.0	0.0	75.0	-19.5	23.3	-15.0	-80.0	35.0
Omalizumab 150mg	48	42.7	26.3	42.5	0.0	100.0	22.1	25.8	10.0	0.0	90.0	-20.6	20.7	-20.0	-80.0	25.0
Omalizumab 300mg	57	42.4	22.4	45.0	0.0	95.0	14.9	18.3	10.0	0.0	65.0	-27.5	22.5	-25.0	-95.0	20.0
Week 24																
Placebo	42	43.5	23.2	45.0	0.0	80.0	19.2	22.0	12.5	0.0	75.0	-24.3	21.9	-20.0	-75.0	20.0
Omalizumab 75mg	45	44.7	23.9	45.0	0.0	80.0	24.1	25.0	15.0	0.0	75.0	-20.6	24.3	-20.0	-80.0	20.0
Omalizumab 150mg	43	42.0	26.6	40.0	0.0	100.0	18.8	26.9	5.0	0.0	90.0	-23.1	21.2	-20.0	-80.0	25.0
Omalizumab 300mg	55	42.3	22.5	45.0	0.0	95.0	13.0	16.1	5.0	0.0	50.0	-29.3	21.1	-25.0	-95.0	10.0
Week 40																
Placebo	36	42.9	23.9	45.0	0.0	80.0	16.8	21.5	7.5	0.0	75.0	-26.1	24.2	-27.5	-80.0	15.0
Omalizumab 75mg	34	41.3	23.6	40.0	0.0	80.0	25.9	26.1	15.0	0.0	90.0	-15.4	21.6	-12.5	-65.0	20.0
Omalizumab 150mg	38	40.5	26.5	37.5	0.0	100.0	28.4	26.8	17.5	0.0	95.0	-12.1	18.4	-10.0	-55.0	25.0
Omalizumab 300mg	38	43.4	22.9	45.0	0.0	90.0	29.9	25.7	27.5	0.0	95.0	-13.6	25.2	-12.5	-60.0	50.0
Early Term																
Placebo	1	50.0		50.0	50.0	50.0	45.0		45.0	45.0	45.0	-5.0		-5.0	-5.0	-5.0
Omalizumab 75mg	1	70.0		70.0	70.0	70.0	80.0		80.0	80.0	80.0	10.0		10.0	10.0	10.0
Omalizumab 150mg	4	51.3	26.6	45.0	30.0	85.0	33.8	25.0	37.5	0.0	60.0	-17.5	32.3	-10.0	-60.0	10.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_cuqol_meanchg)
Database (CLOSED) Datasets (cuqeff)
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Table 14.2/17.2

Mean and Mean Change from Baseline in Chronic Urticaria Quality-of-Life Questionnaire Scores by Study Visit (Observed Data)
Modified Intention to Treat Patients

CU-Q2oL Domain: Looks

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Omalizumab 300mg	3	31.7	28.4	40.0	0.0	55.0	40.0	47.7	15.0	10.0	95.0	8.3	35.5	15.0	-30.0	40.0

The CU-Q2oL is done only in countries where a validated translation was available.
Baseline overall CU-Q2oL and domain scores are based on the measurement taken prior to dosing on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

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Database (CLOSED) Datasets (cuqeff)
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Table 14.2/24
Change from Baseline in EuroQoL-5D Index Score at Week 12 and Week 40 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in EQ-5D index score at Wk 12				
n	63	66	63	70
Mean (SD)	0.09 (0.27)	0.17 (0.25)	0.06 (0.22)	0.20 (0.31)
SE	0.03	0.03	0.03	0.04
Median	0.00	0.14	0.00	0.13
Range	-0.49 - 1.07	-0.47 - 0.88	-0.51 - 0.64	-0.91 - 0.91
95% CI of the Mean	(0.02, 0.16)	(0.10, 0.23)	(0.01, 0.12)	(0.12, 0.27)
Treatment Difference in LS Means* (relative to the Placebo group)		0.06	-0.02	0.13
95% CI of the LS Means Difference		(-0.03, 0.14)	(-0.10, 0.06)	(0.04, 0.22)
p-value^		0.1702	0.6730	0.0062
Change from Baseline in EQ-5D index score at Wk 40				
n	44	47	47	49
Mean (SD)	0.17 (0.27)	0.15 (0.24)	0.08 (0.22)	0.15 (0.29)
SE	0.04	0.04	0.03	0.04
Median	0.18	0.07	0.00	0.12
Range	-0.50 - 1.07	-0.27 - 0.71	-0.40 - 0.63	-0.71 - 0.80
95% CI of the Mean	(0.09, 0.25)	(0.08, 0.22)	(0.01, 0.14)	(0.07, 0.23)
Treatment Difference in LS Means* (relative to the Placebo group)		-0.05	-0.09	-0.00
95% CI of the LS Means Difference		(-0.14, 0.05)	(-0.19, 0.00)	(-0.10, 0.10)
p-value^		0.3281	0.0550	0.9992

Baseline EuroQoL-5D index score is the measurement taken prior to dosing on Day 1.
*The LS mean was estimated using ANCOVA model.The strata are baseline EuroQoL-5D index score (<median vs.>=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_wk_1240)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/25
EuroQol-5D Questionnaire by Study Visit
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Day 1	Mobility	80	76	80	81
	No problems in walking about	66 (82.5%)	61 (80.3%)	69 (86.3%)	70 (86.4%)
	Some problems in walking about	14 (17.5%)	15 (19.7%)	10 (12.5%)	11 (13.6%)
	Confined to bed	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	No response	(0.0%)	(0.0%)	1 (1.3%)	(0.0%)
	Self-care	80	76	80	81
	No problems with self-care	77 (96.3%)	73 (96.1%)	77 (96.3%)	79 (97.5%)
	Some problems washing or dressing myself	3 (3.8%)	3 (3.9%)	3 (3.8%)	2 (2.5%)
	Unable to wash or dress myself	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Usual activity	80	76	80	81
	No problems with performing my usual activities	43 (53.8%)	37 (48.7%)	52 (65.0%)	45 (55.6%)
	Some problems with performing my usual activities	34 (42.5%)	38 (50.0%)	26 (32.5%)	35 (43.2%)
	Unable to perform my usual activities	3 (3.8%)	1 (1.3%)	2 (2.5%)	1 (1.2%)
	Pain/discomfort	80	76	80	81
	No pain or discomfort	17 (21.3%)	20 (26.3%)	22 (27.5%)	15 (18.5%)
	Moderate pain or discomfort	51 (63.8%)	42 (55.3%)	49 (61.3%)	52 (64.2%)
	Extreme pain or discomfort	12 (15.0%)	14 (18.4%)	9 (11.3%)	14 (17.3%)
	Anxiety/depression	80	76	80	81
	Not anxious or depressed	43 (53.8%)	42 (55.3%)	45 (56.3%)	54 (66.7%)
	Moderately anxious or depressed	31 (38.8%)	32 (42.1%)	31 (38.8%)	22 (27.2%)
	Extremely anxious or depressed	6 (7.5%)	2 (2.6%)	4 (5.0%)	4 (4.9%)
	No response	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)
	Health state (VAS)				
	n	80	76	80	81
	Mean (SD)	62.7 (25.4)	67.8 (24.5)	70.1 (19.0)	67.0 (20.3)
	Median	70.0	74.0	72.0	70.0
	Range	1.0 - 100.0	0.0 - 100.0	6.0 - 100.0	4.0 - 100.0

Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_visit)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/25
EuroQol-5D Questionnaire by Study Visit
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Day 1	EuroQol-5D index score				
	n	80	76	79	80
	Mean (SD)	0.66 (0.28)	0.67 (0.28)	0.72 (0.26)	0.68 (0.29)
	Median	0.73	0.73	0.76	0.76
	Range	-0.07 - 1.00	-0.01 - 1.00	-0.07 - 1.00	-0.08 - 1.00
Week 12	Mobility	63	67	63	71
	No problems in walking about	55 (87.3%)	59 (88.1%)	55 (87.3%)	63 (88.7%)
	Some problems in walking about	8 (12.7%)	8 (11.9%)	8 (12.7%)	8 (11.3%)
	Confined to bed	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	No response	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Self-care	63	67	63	71
	No problems with self-care	61 (96.8%)	67 (100.0%)	60 (95.2%)	70 (98.6%)
	Some problems washing or dressing myself	2 (3.2%)	(0.0%)	3 (4.8%)	1 (1.4%)
	Unable to wash or dress myself	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Usual activity	63	67	63	71
	No problems with performing my usual activities	49 (77.8%)	55 (82.1%)	49 (77.8%)	63 (88.7%)
	Some problems with performing my usual activities	12 (19.0%)	11 (16.4%)	12 (19.0%)	7 (9.9%)
	Unable to perform my usual activities	2 (3.2%)	1 (1.5%)	2 (3.2%)	1 (1.4%)
	Pain/discomfort	63	67	63	71
	No pain or discomfort	24 (38.1%)	38 (56.7%)	35 (55.6%)	44 (62.0%)
	Moderate pain or discomfort	37 (58.7%)	25 (37.3%)	24 (38.1%)	26 (36.6%)
	Extreme pain or discomfort	2 (3.2%)	4 (6.0%)	4 (6.3%)	1 (1.4%)
	Anxiety/depression	63	67	63	71
	Not anxious or depressed	41 (65.1%)	48 (71.6%)	42 (66.7%)	58 (81.7%)
	Moderately anxious or depressed	19 (30.2%)	18 (26.9%)	18 (28.6%)	13 (18.3%)
	Extremely anxious or depressed	3 (4.8%)	1 (1.5%)	3 (4.8%)	(0.0%)
	No response	(0.0%)	(0.0%)	(0.0%)	(0.0%)

Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_visit)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/25
EuroQol-5D Questionnaire by Study Visit
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 12	Health state (VAS)				
	n	63	66	63	71
	Mean (SD)	77.1 (19.6)	81.0 (17.7)	75.6 (19.8)	81.7 (12.9)
	Median	80.0	85.0	80.0	85.0
	Range	21.0 - 100.0	20.0 - 100.0	8.0 - 100.0	40.0 - 100.0
	EuroQol-5D index score				
	n	63	67	63	71
	Mean (SD)	0.79 (0.22)	0.83 (0.23)	0.79 (0.26)	0.88 (0.17)
	Median	0.80	0.85	0.85	1.00
	Range	-0.08 - 1.00	0.03 - 1.00	-0.08 - 1.00	0.09 - 1.00
Week 40	Mobility	45	47	47	49
	No problems in walking about	44 (97.8%)	42 (89.4%)	40 (85.1%)	43 (87.8%)
	Some problems in walking about	1 (2.2%)	5 (10.6%)	7 (14.9%)	6 (12.2%)
	Confined to bed	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	No response	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Self-care	45	47	47	49
	No problems with self-care	45 (100.0%)	46 (97.9%)	43 (91.5%)	48 (98.0%)
	Some problems washing or dressing myself	(0.0%)	1 (2.1%)	4 (8.5%)	1 (2.0%)
	Unable to wash or dress myself	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Usual activity	45	47	47	49
	No problems with performing my usual activities	41 (91.1%)	34 (72.3%)	33 (70.2%)	39 (79.6%)
	Some problems with performing my usual activities	4 (8.9%)	13 (27.7%)	13 (27.7%)	10 (20.4%)
	Unable to perform my usual activities	(0.0%)	(0.0%)	1 (2.1%)	(0.0%)
	Pain/discomfort	45	47	47	49
	No pain or discomfort	31 (68.9%)	18 (38.3%)	26 (55.3%)	26 (53.1%)
	Moderate pain or discomfort	13 (28.9%)	26 (55.3%)	19 (40.4%)	22 (44.9%)
	Extreme pain or discomfort	1 (2.2%)	3 (6.4%)	2 (4.3%)	1 (2.0%)

Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_visit)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/25
EuroQol-5D Questionnaire by Study Visit
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 40	Anxiety/depression	45	47	47	49
	Not anxious or depressed	33 (73.3%)	34 (72.3%)	31 (66.0%)	35 (71.4%)
	Moderately anxious or depressed	11 (24.4%)	13 (27.7%)	13 (27.7%)	14 (28.6%)
	Extremely anxious or depressed	(0.0%)	(0.0%)	3 (6.4%)	(0.0%)
	No response	1 (2.2%)	(0.0%)	(0.0%)	(0.0%)
	Health state (VAS)				
	n	45	45	47	47
	Mean (SD)	82.6 (13.3)	81.6 (17.5)	76.9 (20.0)	73.4 (20.2)
	Median	85.0	85.0	85.0	80.0
	Range	40.0 - 100.0	40.0 - 100.0	10.0 - 100.0	7.0 - 100.0
	EuroQol-5D index score				
	n	44	47	47	49
	Mean (SD)	0.89 (0.16)	0.80 (0.20)	0.80 (0.25)	0.85 (0.17)
	Median	1.00	0.80	0.85	0.85
	Range	0.19 - 1.00	0.16 - 1.00	-0.24 - 1.00	0.09 - 1.00
Early Term	Mobility	1	2	4	5
	No problems in walking about	1 (100.0%)	1 (50.0%)	3 (75.0%)	4 (80.0%)
	Some problems in walking about	(0.0%)	1 (50.0%)	1 (25.0%)	1 (20.0%)
	Confined to bed	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	No response	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Self-care	1	2	4	5
	No problems with self-care	1 (100.0%)	2 (100.0%)	4 (100.0%)	4 (80.0%)
	Some problems washing or dressing myself	(0.0%)	(0.0%)	(0.0%)	1 (20.0%)
	Unable to wash or dress myself	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Usual activity	1	2	4	5
	No problems with performing my usual activities	1 (100.0%)	1 (50.0%)	3 (75.0%)	2 (40.0%)
	Some problems with performing my usual activities	(0.0%)	1 (50.0%)	1 (25.0%)	3 (60.0%)

Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_visit)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/25
EuroQol-5D Questionnaire by Study Visit
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Early Term	Unable to perform my usual activities	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Pain/discomfort	1	2	4	5
	No pain or discomfort	(0.0%)	1 (50.0%)	2 (50.0%)	1 (20.0%)
	Moderate pain or discomfort	1 (100.0%)	1 (50.0%)	1 (25.0%)	2 (40.0%)
	Extreme pain or discomfort	(0.0%)	(0.0%)	1 (25.0%)	2 (40.0%)
	Anxiety/depression	1	2	4	5
	Not anxious or depressed	1 (100.0%)	(0.0%)	3 (75.0%)	3 (60.0%)
	Moderately anxious or depressed	(0.0%)	2 (100.0%)	1 (25.0%)	2 (40.0%)
	Extremely anxious or depressed	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	No response	(0.0%)	(0.0%)	(0.0%)	(0.0%)
	Health state (VAS)				
	n	1	2	4	5
	Mean (SD)	70.0 (.)	84.5 (6.4)	58.8 (27.2)	58.0 (31.7)
	Median	70.0	84.5	67.5	70.0
	Range	70.0 - 70.0	80.0 - 89.0	20.0 - 80.0	15.0 - 90.0
	EuroQol-5D index score				
	n	1	2	4	5
	Mean (SD)	0.80 (.)	0.73 (0.06)	0.72 (0.40)	0.54 (0.42)
	Median	0.80	0.73	0.86	0.69
	Range	0.80 - 0.80	0.69 - 0.78	0.16 - 1.00	-0.02 - 1.00

Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eqol_visit)
Database (CLOSED) Datasets (eq5deff pat)
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Table 14.2/26.1
Change from Baseline in MOS Sleep Score at Week 12(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Sleep Disturbance				
n	63	67	63	72
Mean (SD)	-14.7 (24.9)	-18.0 (24.1)	-14.9 (25.9)	-23.5 (25.7)
SE	3.1	2.9	3.3	3.0
Median	-15.0	-15.0	-13.8	-20.0
Range	-68.8 - 47.5	-80.0 - 36.3	-100.0 - 41.3	-95.0 - 26.3
95% CI of the Mean	(-21.0, -8.4)	(-23.8, -12.1)	(-21.5, -8.4)	(-29.5, -17.5)
Treatment Difference in LS Means* (relative to the Placebo group)		-4.0	-1.1	-10.3
95% CI of the LS Means Difference		(-11.7, 3.6)	(-9.5, 7.3)	(-17.9, -2.6)
p-value^		0.2996	0.7922	0.0088
Change from Baseline in Snoring				
n	62	66	61	72
Mean (SD)	0.0 (22.3)	0.0 (25.5)	-4.6 (21.1)	-10.0 (21.2)
SE	2.8	3.1	2.7	2.5
Median	0.0	0.0	0.0	0.0
Range	-60.0 - 40.0	-80.0 - 60.0	-40.0 - 40.0	-80.0 - 20.0
95% CI of the Mean	(-5.7, 5.7)	(-6.3, 6.3)	(-10.0, 0.8)	(-15.0, -5.0)
Treatment Difference in LS Means* (relative to the Placebo group)		0.1	-4.5	-9.8
95% CI of the LS Means Difference		(-8.3, 8.5)	(-12.2, 3.2)	(-17.2, -2.3)
p-value^		0.9770	0.2458	0.0106

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk12)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.1
Change from Baseline in MOS Sleep Score at Week 12(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Short of Breath				
n	63	67	62	72
Mean (SD)	0.0 (25.7)	-10.4 (19.8)	-11.6 (27.5)	-10.6 (32.9)
SE	3.2	2.4	3.5	3.9
Median	0.0	0.0	0.0	0.0
Range	-60.0 - 100.0	-60.0 - 20.0	-100.0 - 20.0	-100.0 - 80.0
95% CI of the Mean	(-6.5, 6.5)	(-15.3, -5.6)	(-18.6, -4.6)	(-18.3, -2.8)
Treatment Difference in LS Means* (relative to the Placebo group)		-6.8	-3.7	-6.2
95% CI of the LS Means Difference		(-13.1, -0.4)	(-12.1, 4.7)	(-15.4, 3.1)
p-value^		0.0365	0.3848	0.1908
Change from Baseline in Sleep Adequacy				
n	63	67	62	72
Mean (SD)	8.6 (21.5)	10.1 (30.1)	7.9 (27.3)	13.3 (33.6)
SE	2.7	3.7	3.5	4.0
Median	10.0	0.0	5.0	10.0
Range	-60.0 - 60.0	-60.0 - 70.0	-50.0 - 100.0	-80.0 - 100.0
95% CI of the Mean	(3.1, 14.0)	(2.8, 17.5)	(1.0, 14.8)	(5.4, 21.2)
Treatment Difference in LS Means* (relative to the Placebo group)		0.4	-1.5	6.4
95% CI of the LS Means Difference		(-8.2, 8.9)	(-9.6, 6.6)	(-2.7, 15.4)
p-value^		0.9297	0.7216	0.1664

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk12)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.1
Change from Baseline in MOS Sleep Score at Week 12(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Somnolence				
n	63	67	63	72
Mean (SD)	-8.6 (23.3)	-12.7 (22.9)	-7.7 (22.7)	-12.3 (18.3)
SE	2.9	2.8	2.9	2.2
Median	-13.3	-6.7	-6.7	-13.3
Range	-66.7 - 40.0	-66.7 - 40.0	-73.3 - 33.3	-60.0 - 20.0
95% CI of the Mean	(-14.4, -2.7)	(-18.3, -7.1)	(-13.4, -2.0)	(-16.6, -8.0)
Treatment Difference in LS Means* (relative to the Placebo group)		-2.6	1.3	-4.2
95% CI of the LS Means Difference		(-9.8, 4.6)	(-6.2, 8.9)	(-10.7, 2.4)
p-value^		0.4721	0.7248	0.2128
Change from Baseline in Sleep Problems Index I				
n	63	67	63	72
Mean (SD)	-8.6 (16.9)	-13.6 (17.5)	-10.8 (20.5)	-16.1 (21.7)
SE	2.1	2.1	2.6	2.6
Median	-6.7	-10.0	-10.0	-11.7
Range	-53.3 - 33.3	-56.7 - 20.0	-100.0 - 40.0	-83.3 - 20.0
95% CI of the Mean	(-12.8, -4.3)	(-17.8, -9.3)	(-16.0, -5.6)	(-21.2, -11.0)
Treatment Difference in LS Means* (relative to the Placebo group)		-4.1	-2.1	-7.7
95% CI of the LS Means Difference		(-9.9, 1.6)	(-8.3, 4.2)	(-13.8, -1.6)
p-value^		0.1547	0.5166	0.0138

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk12)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.1
Change from Baseline in MOS Sleep Score at Week 12(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Sleep Problems Index II				
n	63	67	63	72
Mean (SD)	-10.7 (18.0)	-14.4 (18.6)	-11.8 (20.6)	-18.1 (21.6)
SE	2.3	2.3	2.6	2.5
Median	-11.1	-8.9	-9.4	-13.6
Range	-50.0 - 27.2	-64.4 - 29.4	-100.0 - 40.6	-78.9 - 16.1
95% CI of the Mean	(-15.2, -6.2)	(-18.9, -9.8)	(-17.0, -6.6)	(-23.2, -13.1)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.2	-0.7	-7.2
95% CI of the LS Means Difference		(-9.2, 2.8)	(-7.2, 5.7)	(-13.5, -0.9)
p-value^		0.2952	0.8194	0.0248
Change from Baseline in Sleep Quantity				
n	62	67	62	71
Mean (SD)	0.3 (1.1)	0.6 (1.3)	0.6 (1.8)	0.2 (1.2)
SE	0.1	0.2	0.2	0.1
Median	0.0	1.0	0.0	0.0
Range	-2.0 - 2.0	-2.0 - 4.0	-2.0 - 8.0	-2.0 - 4.0
95% CI of the Mean	(0.1, 0.6)	(0.3, 0.9)	(0.2, 1.1)	(-0.0, 0.5)
Treatment Difference in LS Means* (relative to the Placebo group)		0.2	0.4	-0.1
95% CI of the LS Means Difference		(-0.2, 0.6)	(-0.1, 0.8)	(-0.4, 0.3)
p-value^		0.3159	0.1348	0.7226

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk12)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.1
Change from Baseline in MOS Sleep Score at Week 12(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Optimal Sleep				
n	62	67	62	71
Mean (SD)	0.1 (0.6)	0.3 (0.5)	0.0 (0.6)	0.0 (0.6)
SE	0.1	0.1	0.1	0.1
Median	0.0	0.0	0.0	0.0
Range	-1.0 - 1.0	-1.0 - 1.0	-1.0 - 1.0	-1.0 - 1.0
95% CI of the Mean	(-0.0, 0.3)	(0.2, 0.5)	(-0.1, 0.2)	(-0.1, 0.2)
Treatment Difference in LS Means* (relative to the Placebo group)		0.2	-0.1	-0.0
95% CI of the LS Means Difference		(0.0, 0.4)	(-0.3, 0.1)	(-0.2, 0.2)
p-value^		0.0256	0.5293	0.7046

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk12)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Disturbance

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	52.1	25.0	52.5	5.0	100.0	52.1	25.0	52.5	5.0	100.0					
Omalizumab 75mg	76	49.6	26.1	46.3	0.0	100.0	49.6	26.1	46.3	0.0	100.0					
Omalizumab 150mg	80	49.0	26.1	47.5	0.0	100.0	49.0	26.1	47.5	0.0	100.0					
Omalizumab 300mg	81	51.0	24.9	50.0	0.0	100.0	51.0	24.9	50.0	0.0	100.0					
Week 4																
Placebo	73	52.5	25.3	52.5	5.0	100.0	39.9	24.9	32.5	0.0	95.0	-12.6	21.3	-10.0	-62.5	46.3
Omalizumab 75mg	71	50.1	26.0	46.3	0.0	100.0	40.5	23.4	36.3	0.0	100.0	-9.6	18.5	-10.0	-53.8	41.3
Omalizumab 150mg	77	49.0	26.3	47.5	0.0	100.0	39.1	26.6	31.3	0.0	100.0	-10.0	23.4	-10.0	-100.0	70.0
Omalizumab 300mg	76	52.5	24.4	51.3	5.0	100.0	33.9	24.3	30.0	0.0	95.0	-18.6	23.7	-14.4	-95.0	26.3
Week 12																
Placebo	63	50.9	25.5	51.3	5.0	100.0	36.2	25.1	26.3	0.0	100.0	-14.7	24.9	-15.0	-68.8	47.5
Omalizumab 75mg	67	51.1	26.4	52.5	5.0	100.0	33.1	24.5	26.3	0.0	90.0	-18.0	24.1	-15.0	-80.0	36.3
Omalizumab 150mg	63	49.0	25.4	47.5	0.0	100.0	34.1	26.3	30.0	0.0	95.0	-14.9	25.9	-13.8	-100.0	41.3
Omalizumab 300mg	72	52.1	24.6	50.6	5.0	100.0	28.6	22.7	26.3	0.0	100.0	-23.5	25.7	-20.0	-95.0	26.3
Week 24																
Placebo	51	50.4	25.4	51.3	5.0	95.0	31.9	23.4	26.3	0.0	93.8	-18.5	25.7	-16.3	-93.8	32.5
Omalizumab 75mg	60	51.4	26.0	49.4	5.0	100.0	32.6	24.7	31.3	0.0	95.0	-18.8	23.6	-15.0	-95.0	36.3
Omalizumab 150mg	55	48.7	25.1	50.0	0.0	100.0	29.8	23.9	26.3	0.0	85.0	-18.9	28.7	-16.3	-100.0	57.5
Omalizumab 300mg	69	51.3	23.8	50.0	5.0	100.0	27.2	24.8	21.3	0.0	100.0	-24.1	25.7	-25.0	-87.5	41.3
Week 40																
Placebo	45	50.1	25.6	51.3	5.0	95.0	29.5	23.2	26.3	0.0	78.8	-20.5	24.9	-16.3	-78.8	26.3
Omalizumab 75mg	47	53.5	26.4	52.5	5.0	100.0	31.9	23.4	26.3	0.0	85.0	-21.6	24.9	-16.3	-95.0	10.0
Omalizumab 150mg	49	51.2	24.2	52.5	5.0	100.0	39.4	24.7	36.3	5.0	100.0	-11.8	24.6	-15.0	-62.5	52.5
Omalizumab 300mg	50	52.6	23.7	51.3	5.0	100.0	33.6	21.9	29.4	0.0	88.8	-19.1	25.1	-20.0	-66.3	47.5

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Disturbance

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	20.0		20.0	20.0	20.0	10.0		10.0	10.0	10.0	-10.0		-10.0	-10.0	-10.0
Omalizumab 75mg	2	43.8	3.5	43.8	41.3	46.3	46.9	8.0	46.9	41.3	52.5	3.1	4.4	3.1	0.0	6.3
Omalizumab 150mg	4	34.1	33.3	28.8	0.0	78.8	36.3	23.3	36.3	10.0	62.5	2.2	19.7	-0.6	-16.3	26.3
Omalizumab 300mg	4	31.6	11.6	28.8	21.3	47.5	47.2	18.4	41.9	31.3	73.8	15.6	26.3	7.5	-5.0	52.5

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Snoring

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	31.8	29.6	20.0	0.0	100.0	31.8	29.6	20.0	0.0	100.0					
Omalizumab 75mg	76	35.5	33.4	20.0	0.0	100.0	35.5	33.4	20.0	0.0	100.0					
Omalizumab 150mg	80	36.0	31.7	40.0	0.0	100.0	36.0	31.7	40.0	0.0	100.0					
Omalizumab 300mg	81	39.5	33.2	40.0	0.0	100.0	39.5	33.2	40.0	0.0	100.0					
Week 4																
Placebo	71	29.9	28.9	20.0	0.0	100.0	28.5	30.2	20.0	0.0	100.0	-1.4	23.0	0.0	-80.0	60.0
Omalizumab 75mg	71	36.6	34.1	20.0	0.0	100.0	34.1	33.2	20.0	0.0	100.0	-2.5	23.6	0.0	-80.0	80.0
Omalizumab 150mg	76	37.4	31.9	40.0	0.0	100.0	33.9	34.3	20.0	0.0	100.0	-3.4	20.5	0.0	-60.0	40.0
Omalizumab 300mg	75	40.8	33.1	40.0	0.0	100.0	32.8	30.4	20.0	0.0	100.0	-8.0	18.3	0.0	-60.0	20.0
Week 12																
Placebo	62	29.7	28.9	20.0	0.0	100.0	29.7	28.7	20.0	0.0	100.0	0.0	22.3	0.0	-60.0	40.0
Omalizumab 75mg	66	36.4	33.4	20.0	0.0	100.0	36.4	34.9	30.0	0.0	100.0	0.0	25.5	0.0	-80.0	60.0
Omalizumab 150mg	61	37.0	31.8	40.0	0.0	100.0	32.5	31.7	20.0	0.0	100.0	-4.6	21.1	0.0	-40.0	40.0
Omalizumab 300mg	72	40.3	33.0	40.0	0.0	100.0	30.3	30.6	20.0	0.0	100.0	-10.0	21.2	0.0	-80.0	20.0
Week 24																
Placebo	51	29.8	30.0	20.0	0.0	100.0	29.4	30.0	20.0	0.0	100.0	-0.4	25.1	0.0	-60.0	60.0
Omalizumab 75mg	59	36.6	33.7	20.0	0.0	100.0	33.9	32.9	20.0	0.0	100.0	-2.7	24.5	0.0	-80.0	60.0
Omalizumab 150mg	55	37.1	31.4	40.0	0.0	100.0	32.4	34.7	20.0	0.0	100.0	-4.7	28.0	0.0	-100.0	100.0
Omalizumab 300mg	68	39.1	32.7	40.0	0.0	100.0	30.6	30.8	20.0	0.0	100.0	-8.5	20.8	0.0	-80.0	40.0
Week 40																
Placebo	45	29.3	30.3	20.0	0.0	100.0	27.6	27.7	20.0	0.0	100.0	-1.8	25.5	0.0	-80.0	60.0
Omalizumab 75mg	47	40.0	33.6	40.0	0.0	100.0	36.6	36.2	40.0	0.0	100.0	-3.4	24.1	0.0	-80.0	60.0
Omalizumab 150mg	49	33.5	29.5	40.0	0.0	100.0	29.8	28.9	20.0	0.0	100.0	-3.7	23.3	0.0	-100.0	40.0
Omalizumab 300mg	49	38.4	31.3	40.0	0.0	100.0	28.6	28.6	20.0	0.0	100.0	-9.8	22.0	0.0	-80.0	20.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Snoring

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	40.0		40.0	40.0	40.0	20.0		20.0	20.0	20.0	-20.0		-20.0	-20.0	-20.0
Omalizumab 75mg	2	50.0	14.1	50.0	40.0	60.0	50.0	14.1	50.0	40.0	60.0	0.0	0.0	0.0	0.0	0.0
Omalizumab 150mg	3	86.7	11.5	80.0	80.0	100.0	66.7	41.6	80.0	20.0	100.0	-20.0	40.0	-20.0	-60.0	20.0
Omalizumab 300mg	4	35.0	25.2	40.0	0.0	60.0	45.0	25.2	40.0	20.0	80.0	10.0	25.8	10.0	-20.0	40.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Short of Breath

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	17.0	25.3	0.0	0.0	100.0	17.0	25.3	0.0	0.0	100.0					
Omalizumab 75mg	76	20.0	25.1	0.0	0.0	100.0	20.0	25.1	0.0	0.0	100.0					
Omalizumab 150mg	80	27.5	29.6	20.0	0.0	100.0	27.5	29.6	20.0	0.0	100.0					
Omalizumab 300mg	80	22.3	27.0	20.0	0.0	100.0	22.3	27.0	20.0	0.0	100.0					
Week 4																
Placebo	73	17.8	25.9	0.0	0.0	100.0	12.6	19.3	0.0	0.0	100.0	-5.2	22.1	0.0	-100.0	40.0
Omalizumab 75mg	71	20.0	23.7	20.0	0.0	80.0	13.5	21.6	0.0	0.0	80.0	-6.5	24.6	0.0	-80.0	60.0
Omalizumab 150mg	77	27.5	29.2	20.0	0.0	100.0	19.7	27.8	0.0	0.0	100.0	-7.8	27.0	0.0	-100.0	80.0
Omalizumab 300mg	76	23.4	27.2	20.0	0.0	100.0	15.3	23.3	0.0	0.0	100.0	-8.2	28.1	0.0	-100.0	60.0
Week 12																
Placebo	63	15.9	25.2	0.0	0.0	100.0	15.9	24.4	0.0	0.0	100.0	0.0	25.7	0.0	-60.0	100.0
Omalizumab 75mg	67	19.7	24.0	0.0	0.0	80.0	9.3	14.1	0.0	0.0	60.0	-10.4	19.8	0.0	-60.0	20.0
Omalizumab 150mg	62	27.7	27.9	20.0	0.0	100.0	16.1	23.1	0.0	0.0	80.0	-11.6	27.5	0.0	-100.0	20.0
Omalizumab 300mg	72	23.3	27.5	20.0	0.0	100.0	12.8	23.1	0.0	0.0	100.0	-10.6	32.9	0.0	-100.0	80.0
Week 24																
Placebo	51	15.3	25.8	0.0	0.0	100.0	16.1	25.3	0.0	0.0	100.0	0.8	21.9	0.0	-60.0	80.0
Omalizumab 75mg	60	19.3	23.3	10.0	0.0	80.0	13.3	22.0	0.0	0.0	100.0	-6.0	25.1	0.0	-60.0	80.0
Omalizumab 150mg	55	27.6	28.4	20.0	0.0	100.0	13.8	24.6	0.0	0.0	100.0	-13.8	28.8	0.0	-100.0	40.0
Omalizumab 300mg	69	23.2	27.8	20.0	0.0	100.0	10.4	18.7	0.0	0.0	80.0	-12.8	28.3	0.0	-100.0	40.0
Week 40																
Placebo	45	14.2	23.6	0.0	0.0	80.0	12.4	20.6	0.0	0.0	80.0	-1.8	18.5	0.0	-40.0	40.0
Omalizumab 75mg	47	19.6	22.6	20.0	0.0	60.0	14.0	20.0	0.0	0.0	60.0	-5.5	26.3	0.0	-60.0	40.0
Omalizumab 150mg	48	29.6	29.5	20.0	0.0	100.0	17.5	23.6	10.0	0.0	100.0	-12.1	24.0	0.0	-80.0	20.0
Omalizumab 300mg	50	23.2	27.5	20.0	0.0	100.0	16.0	20.2	0.0	0.0	60.0	-7.2	27.3	0.0	-100.0	40.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Short of Breath

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	0.0		0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0		0.0	0.0	0.0
Omalizumab 75mg	2	30.0	14.1	30.0	20.0	40.0	0.0	0.0	0.0	0.0	0.0	-30.0	14.1	-30.0	-40.0	-20.0
Omalizumab 150mg	3	20.0	34.6	0.0	0.0	60.0	40.0	52.9	20.0	0.0	100.0	20.0	80.0	20.0	-60.0	100.0
Omalizumab 300mg	4	10.0	20.0	0.0	0.0	40.0	20.0	23.1	20.0	0.0	40.0	10.0	38.3	20.0	-40.0	40.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Adequacy

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	40.8	26.2	40.0	0.0	90.0	40.8	26.2	40.0	0.0	90.0					
Omalizumab 75mg	76	37.2	20.7	35.0	0.0	90.0	37.2	20.7	35.0	0.0	90.0					
Omalizumab 150mg	80	38.3	25.3	35.0	0.0	90.0	38.3	25.3	35.0	0.0	90.0					
Omalizumab 300mg	81	42.7	26.0	40.0	0.0	100.0	42.7	26.0	40.0	0.0	100.0					
Week 4																
Placebo	73	40.5	27.0	40.0	0.0	90.0	49.0	25.6	50.0	0.0	100.0	8.5	23.4	10.0	-60.0	70.0
Omalizumab 75mg	71	36.3	21.1	30.0	0.0	90.0	42.3	27.0	40.0	0.0	100.0	5.9	26.5	0.0	-50.0	70.0
Omalizumab 150mg	77	38.6	25.3	40.0	0.0	90.0	41.9	27.1	40.0	0.0	100.0	3.4	25.0	0.0	-80.0	100.0
Omalizumab 300mg	76	41.3	25.5	40.0	0.0	100.0	53.9	25.3	50.0	0.0	100.0	12.6	27.6	10.0	-60.0	90.0
Week 12																
Placebo	63	42.2	26.3	40.0	0.0	90.0	50.8	26.2	50.0	0.0	100.0	8.6	21.5	10.0	-60.0	60.0
Omalizumab 75mg	67	36.7	20.9	30.0	0.0	90.0	46.9	26.2	50.0	0.0	100.0	10.1	30.1	0.0	-60.0	70.0
Omalizumab 150mg	62	39.4	25.5	40.0	0.0	90.0	47.3	27.2	40.0	0.0	100.0	7.9	27.3	5.0	-50.0	100.0
Omalizumab 300mg	72	41.8	25.9	40.0	0.0	100.0	55.1	25.6	50.0	0.0	100.0	13.3	33.6	10.0	-80.0	100.0
Week 24																
Placebo	51	39.6	25.5	40.0	0.0	90.0	51.6	24.1	50.0	0.0	90.0	12.0	25.3	10.0	-40.0	80.0
Omalizumab 75mg	60	36.7	21.0	30.0	0.0	90.0	43.5	24.3	40.0	0.0	100.0	6.8	25.7	10.0	-60.0	70.0
Omalizumab 150mg	55	39.5	26.0	40.0	0.0	90.0	53.1	26.4	50.0	0.0	100.0	13.6	25.7	10.0	-40.0	100.0
Omalizumab 300mg	69	42.3	25.6	40.0	0.0	100.0	55.8	26.8	60.0	0.0	100.0	13.5	34.8	10.0	-80.0	100.0
Week 40																
Placebo	45	41.8	24.0	40.0	0.0	90.0	53.6	25.2	60.0	0.0	100.0	11.8	25.5	10.0	-40.0	70.0
Omalizumab 75mg	47	37.2	19.3	40.0	0.0	90.0	52.1	28.2	50.0	0.0	100.0	14.9	27.1	10.0	-50.0	70.0
Omalizumab 150mg	49	37.6	25.0	30.0	0.0	90.0	47.1	26.7	40.0	0.0	90.0	9.6	26.8	0.0	-50.0	70.0
Omalizumab 300mg	50	44.2	25.6	40.0	0.0	100.0	53.8	24.0	55.0	0.0	100.0	9.6	30.4	10.0	-80.0	100.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Adequacy

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	60.0		60.0	60.0	60.0	80.0		80.0	80.0	80.0	20.0		20.0	20.0	20.0
Omalizumab 75mg	2	35.0	7.1	35.0	30.0	40.0	55.0	7.1	55.0	50.0	60.0	20.0	14.1	20.0	10.0	30.0
Omalizumab 150mg	3	56.7	49.3	80.0	0.0	90.0	30.0	20.0	30.0	10.0	50.0	-26.7	32.1	-40.0	-50.0	10.0
Omalizumab 300mg	4	52.5	37.7	50.0	10.0	100.0	42.5	22.2	50.0	10.0	60.0	-10.0	21.6	-5.0	-40.0	10.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Somnolence

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	39.0	21.8	40.0	0.0	80.0	39.0	21.8	40.0	0.0	80.0					
Omalizumab 75mg	76	43.4	25.6	40.0	0.0	100.0	43.4	25.6	40.0	0.0	100.0					
Omalizumab 150mg	80	42.0	20.7	40.0	0.0	86.7	42.0	20.7	40.0	0.0	86.7					
Omalizumab 300mg	81	38.2	20.1	40.0	0.0	100.0	38.2	20.1	40.0	0.0	100.0					
Week 4																
Placebo	73	40.0	22.1	40.0	0.0	80.0	32.4	23.0	26.7	0.0	100.0	-7.6	20.9	-6.7	-66.7	53.3
Omalizumab 75mg	71	44.5	25.8	40.0	0.0	100.0	35.3	26.0	33.3	0.0	100.0	-9.2	19.6	-6.7	-46.7	40.0
Omalizumab 150mg	77	42.1	20.7	40.0	0.0	86.7	35.1	22.3	26.7	0.0	100.0	-7.0	19.3	-6.7	-66.7	46.7
Omalizumab 300mg	76	38.9	19.8	40.0	0.0	100.0	27.1	18.8	20.0	0.0	100.0	-11.8	15.7	-6.7	-60.0	20.0
Week 12																
Placebo	63	39.9	21.7	40.0	0.0	80.0	31.3	24.0	26.7	0.0	93.3	-8.6	23.3	-13.3	-66.7	40.0
Omalizumab 75mg	67	44.1	26.3	40.0	0.0	100.0	31.3	25.9	26.7	0.0	100.0	-12.7	22.9	-6.7	-66.7	40.0
Omalizumab 150mg	63	41.8	21.9	40.0	0.0	86.7	34.1	21.1	33.3	0.0	86.7	-7.7	22.7	-6.7	-73.3	33.3
Omalizumab 300mg	72	38.8	20.0	40.0	0.0	100.0	26.5	19.2	26.7	0.0	86.7	-12.3	18.3	-13.3	-60.0	20.0
Week 24																
Placebo	51	39.6	22.2	40.0	0.0	80.0	30.5	20.2	26.7	0.0	86.7	-9.2	21.6	-6.7	-66.7	33.3
Omalizumab 75mg	60	43.6	25.8	40.0	0.0	100.0	32.6	23.5	26.7	0.0	100.0	-11.0	25.1	-6.7	-80.0	46.7
Omalizumab 150mg	55	42.1	22.0	40.0	0.0	86.7	27.4	21.6	20.0	0.0	80.0	-14.7	23.1	-13.3	-80.0	33.3
Omalizumab 300mg	69	39.0	19.6	40.0	0.0	100.0	27.3	20.3	20.0	0.0	80.0	-11.7	21.2	-13.3	-86.7	40.0
Week 40																
Placebo	45	39.1	21.9	40.0	0.0	80.0	26.1	19.9	20.0	0.0	73.3	-13.0	22.6	-6.7	-66.7	33.3
Omalizumab 75mg	47	42.6	25.2	40.0	0.0	100.0	31.5	24.1	26.7	0.0	100.0	-11.1	24.5	-6.7	-73.3	40.0
Omalizumab 150mg	49	41.8	21.2	40.0	0.0	80.0	36.1	23.6	33.3	0.0	100.0	-5.7	18.7	-6.7	-40.0	40.0
Omalizumab 300mg	50	38.5	18.1	40.0	0.0	80.0	28.1	19.9	26.7	0.0	93.3	-10.4	22.7	-13.3	-46.7	66.7

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Somnolence

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	33.3		33.3	33.3	33.3	20.0		20.0	20.0	20.0	-13.3		-13.3	-13.3	-13.3
Omalizumab 75mg	2	43.3	4.7	43.3	40.0	46.7	43.3	33.0	43.3	20.0	66.7	0.0	28.3	0.0	-20.0	20.0
Omalizumab 150mg	4	46.7	9.4	43.3	40.0	60.0	50.0	8.6	50.0	40.0	60.0	3.3	15.9	10.0	-20.0	13.3
Omalizumab 300mg	4	30.0	17.6	26.7	13.3	53.3	26.7	16.3	30.0	6.7	40.0	-3.3	20.7	-3.3	-26.7	20.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Problems Index I

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	45.2	19.7	43.3	6.7	93.3	45.2	19.7	43.3	6.7	93.3					
Omalizumab 75mg	76	47.0	16.5	46.7	16.7	86.7	47.0	16.5	46.7	16.7	86.7					
Omalizumab 150mg	80	47.7	21.6	45.0	6.7	100.0	47.7	21.6	45.0	6.7	100.0					
Omalizumab 300mg	81	44.8	19.1	43.3	6.7	86.7	44.8	19.1	43.3	6.7	86.7					
Week 4																
Placebo	73	45.9	20.2	46.7	6.7	93.3	36.9	20.5	40.0	3.3	76.7	-9.0	15.2	-6.7	-56.7	16.7
Omalizumab 75mg	71	47.7	16.3	46.7	16.7	86.7	39.9	19.3	40.0	6.7	86.7	-7.7	15.3	-3.3	-46.7	36.7
Omalizumab 150mg	77	47.8	21.9	43.3	6.7	100.0	40.1	21.1	36.7	6.7	93.3	-7.7	17.4	-6.7	-93.3	30.0
Omalizumab 300mg	76	46.0	19.0	46.7	6.7	86.7	32.2	19.4	30.0	0.0	80.0	-13.8	18.0	-8.3	-66.7	13.3
Week 12																
Placebo	63	44.3	19.6	43.3	6.7	93.3	35.7	21.1	33.3	0.0	86.7	-8.6	16.9	-6.7	-53.3	33.3
Omalizumab 75mg	67	47.8	16.2	50.0	16.7	86.7	34.2	17.4	33.3	0.0	76.7	-13.6	17.5	-10.0	-56.7	20.0
Omalizumab 150mg	63	47.4	21.1	43.3	6.7	100.0	36.6	18.7	36.7	0.0	76.7	-10.8	20.5	-10.0	-100.0	40.0
Omalizumab 300mg	72	45.6	19.1	45.0	6.7	86.7	29.5	18.3	28.3	0.0	90.0	-16.1	21.7	-11.7	-83.3	20.0
Week 24																
Placebo	51	44.8	20.1	43.3	6.7	93.3	32.6	19.9	26.7	3.3	80.0	-12.2	20.0	-13.3	-83.3	26.7
Omalizumab 75mg	60	47.7	15.4	48.3	16.7	83.3	36.0	19.3	33.3	6.7	96.7	-11.7	16.2	-10.0	-43.3	43.3
Omalizumab 150mg	55	47.5	21.5	43.3	6.7	100.0	31.6	18.2	33.3	0.0	66.7	-15.9	22.0	-13.3	-100.0	40.0
Omalizumab 300mg	69	45.3	18.4	43.3	6.7	86.7	28.9	19.3	23.3	0.0	90.0	-16.4	20.8	-13.3	-83.3	26.7
Week 40																
Placebo	45	43.5	20.4	43.3	6.7	93.3	30.3	20.0	23.3	0.0	76.7	-13.2	18.1	-10.0	-60.0	20.0
Omalizumab 75mg	47	47.8	15.7	50.0	16.7	83.3	32.5	19.9	30.0	3.3	83.3	-15.3	17.8	-13.3	-53.3	16.7
Omalizumab 150mg	49	49.7	20.7	46.7	13.3	100.0	38.8	20.7	40.0	10.0	100.0	-10.9	19.8	-13.3	-53.3	50.0
Omalizumab 300mg	50	44.7	18.5	43.3	13.3	83.3	32.8	18.1	30.0	3.3	73.3	-11.9	19.3	-11.7	-66.7	33.3

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Problems Index I

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	23.3		23.3	23.3	23.3	10.0		10.0	10.0	10.0	-13.3		-13.3	-13.3	-13.3
Omalizumab 75mg	2	50.0	4.7	50.0	46.7	53.3	36.7	9.4	36.7	30.0	43.3	-13.3	4.7	-13.3	-16.7	-10.0
Omalizumab 150mg	3	35.6	39.1	20.0	6.7	80.0	51.1	5.1	50.0	46.7	56.7	15.6	34.0	30.0	-23.3	40.0
Omalizumab 300mg	4	33.3	15.6	31.7	16.7	53.3	42.5	15.0	38.3	30.0	63.3	9.2	11.0	13.3	-6.7	16.7

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Problems Index II

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	47.8	19.8	47.8	8.9	92.8	47.8	19.8	47.8	8.9	92.8					
Omalizumab 75mg	76	48.4	17.8	48.9	13.3	86.7	48.4	17.8	48.9	13.3	86.7					
Omalizumab 150mg	80	49.2	21.2	50.0	8.9	100.0	49.2	21.2	50.0	8.9	100.0					
Omalizumab 300mg	81	47.4	19.3	48.3	11.1	91.1	47.4	19.3	48.3	11.1	91.1					
Week 4																
Placebo	73	48.3	20.3	50.0	8.9	92.8	38.3	20.5	36.7	2.2	84.4	-10.0	16.1	-8.9	-56.7	25.0
Omalizumab 75mg	71	49.0	17.7	49.4	13.3	86.7	40.7	19.3	41.1	6.7	91.1	-8.3	14.5	-6.7	-47.2	33.9
Omalizumab 150mg	77	49.2	21.5	49.4	8.9	100.0	41.2	21.0	37.8	4.4	92.8	-8.0	17.8	-6.7	-95.6	37.8
Omalizumab 300mg	76	48.7	19.1	49.7	11.1	91.1	33.6	19.2	28.9	2.2	76.7	-15.1	18.0	-9.4	-68.9	13.3
Week 12																
Placebo	63	46.8	20.1	45.0	8.9	92.8	36.1	21.1	33.3	0.0	86.1	-10.7	18.0	-11.1	-50.0	27.2
Omalizumab 75mg	67	49.3	17.6	49.4	17.8	86.7	34.9	18.4	33.3	0.0	77.8	-14.4	18.6	-8.9	-64.4	29.4
Omalizumab 150mg	63	48.9	20.8	47.2	8.9	100.0	37.1	19.5	33.3	0.0	80.0	-11.8	20.6	-9.4	-100.0	40.6
Omalizumab 300mg	72	48.4	19.3	48.9	11.1	91.1	30.3	18.4	28.1	0.0	93.3	-18.1	21.6	-13.6	-78.9	16.1
Week 24																
Placebo	51	47.2	20.7	45.0	8.9	92.8	33.7	19.7	26.7	4.4	80.0	-13.4	19.5	-10.6	-83.9	20.0
Omalizumab 75mg	60	49.4	16.9	48.9	17.8	86.7	36.3	20.0	31.4	6.7	95.0	-13.0	17.1	-11.7	-52.8	35.6
Omalizumab 150mg	55	48.7	20.8	49.4	8.9	100.0	32.1	18.7	29.4	0.0	73.3	-16.7	22.1	-13.9	-100.0	41.1
Omalizumab 300mg	69	48.0	18.6	48.3	11.1	91.1	29.5	19.2	26.7	0.0	91.1	-18.5	20.3	-18.3	-78.9	27.2
Week 40																
Placebo	45	46.2	20.8	45.0	8.9	92.8	31.3	20.0	27.2	0.0	74.4	-14.9	19.7	-9.4	-66.1	25.0
Omalizumab 75mg	47	49.5	17.3	48.3	17.8	86.7	33.3	20.0	27.2	4.4	77.8	-16.3	18.2	-13.3	-64.4	15.6
Omalizumab 150mg	49	50.7	20.2	51.1	13.3	100.0	40.6	20.2	38.3	8.9	100.0	-10.1	18.6	-11.1	-52.2	45.6
Omalizumab 300mg	50	47.9	18.5	49.2	15.6	86.1	33.6	17.9	30.8	4.4	75.0	-14.3	19.9	-13.3	-57.8	36.7

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Problems Index II

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	22.2		22.2	22.2	22.2	13.3		13.3	13.3	13.3	-8.9		-8.9	-8.9	-8.9
Omalizumab 75mg	2	49.4	0.0	49.4	49.4	49.4	41.9	11.4	41.9	33.9	50.0	-7.5	11.4	-7.5	-15.6	0.6
Omalizumab 150mg	4	37.9	32.3	29.4	8.9	83.9	47.8	11.2	47.4	35.6	61.1	9.9	23.5	17.6	-22.8	27.2
Omalizumab 300mg	4	34.6	15.5	33.9	18.9	51.7	43.8	15.6	38.3	32.2	66.1	9.2	13.6	14.7	-11.1	18.3

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Quantity

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	6.3	1.4	6.0	1.0	10.0	6.3	1.4	6.0	1.0	10.0					
Omalizumab 75mg	76	6.2	1.6	6.0	1.0	10.0	6.2	1.6	6.0	1.0	10.0					
Omalizumab 150mg	79	6.4	1.6	6.0	1.0	12.0	6.4	1.6	6.0	1.0	12.0					
Omalizumab 300mg	80	6.5	1.2	7.0	4.0	9.0	6.5	1.2	7.0	4.0	9.0					
Week 4																
Placebo	73	6.3	1.4	6.0	1.0	10.0	6.5	1.5	6.0	2.0	12.0	0.2	1.2	0.0	-2.0	4.0
Omalizumab 75mg	70	6.2	1.6	6.0	1.0	10.0	6.5	1.3	6.5	3.0	9.0	0.3	1.2	0.0	-3.0	3.0
Omalizumab 150mg	76	6.4	1.6	6.0	1.0	12.0	6.8	1.3	7.0	2.0	12.0	0.4	1.4	0.0	-3.0	8.0
Omalizumab 300mg	75	6.5	1.2	7.0	4.0	9.0	6.8	1.1	7.0	4.0	9.0	0.3	1.0	0.0	-3.0	4.0
Week 12																
Placebo	62	6.3	1.2	6.0	3.0	10.0	6.6	1.2	7.0	3.0	9.0	0.3	1.1	0.0	-2.0	2.0
Omalizumab 75mg	67	6.2	1.6	6.0	1.0	10.0	6.7	1.3	7.0	3.0	9.0	0.6	1.3	1.0	-2.0	4.0
Omalizumab 150mg	62	6.4	1.6	6.0	1.0	12.0	7.0	1.4	7.0	4.0	12.0	0.6	1.8	0.0	-2.0	8.0
Omalizumab 300mg	71	6.5	1.3	7.0	4.0	9.0	6.7	1.2	7.0	4.0	9.0	0.2	1.2	0.0	-2.0	4.0
Week 24																
Placebo	51	6.3	1.3	6.0	3.0	10.0	6.7	1.2	7.0	4.0	9.0	0.4	1.1	0.0	-2.0	2.0
Omalizumab 75mg	60	6.2	1.7	6.0	1.0	10.0	6.7	1.2	7.0	4.0	9.0	0.5	1.5	0.0	-3.0	7.0
Omalizumab 150mg	53	6.4	1.6	6.0	1.0	12.0	7.0	1.2	7.0	4.0	10.0	0.6	1.5	0.0	-2.0	7.0
Omalizumab 300mg	67	6.5	1.2	7.0	4.0	9.0	6.8	1.1	7.0	4.0	9.0	0.2	1.2	0.0	-2.0	3.0
Week 40																
Placebo	44	6.3	1.3	6.0	4.0	10.0	6.7	1.1	7.0	4.0	9.0	0.4	1.3	0.0	-3.0	4.0
Omalizumab 75mg	45	6.2	1.8	6.0	1.0	10.0	6.9	1.2	7.0	4.0	10.0	0.7	1.8	0.0	-2.0	7.0
Omalizumab 150mg	47	6.1	1.5	6.0	1.0	9.0	6.5	1.3	6.0	3.0	9.0	0.4	1.7	0.0	-3.0	7.0
Omalizumab 300mg	49	6.7	1.2	7.0	4.0	9.0	7.0	1.1	7.0	5.0	9.0	0.3	1.4	0.0	-3.0	4.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Sleep Quantity

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	6.0		6.0	6.0	6.0	7.0		7.0	7.0	7.0	1.0		1.0	1.0	1.0
Omalizumab 75mg	2	6.0	0.0	6.0	6.0	6.0	7.0	1.4	7.0	6.0	8.0	1.0	1.4	1.0	0.0	2.0
Omalizumab 150mg	4	8.0	2.7	7.0	6.0	12.0	6.8	2.2	6.0	5.0	10.0	-1.3	1.0	-1.5	-2.0	0.0
Omalizumab 300mg	4	6.5	1.3	6.5	5.0	8.0	6.5	1.3	6.5	5.0	8.0	0.0	0.0	0.0	0.0	0.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Optimal Sleep

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Day 1																
Placebo	80	0.4	0.5	0.0	0.0	1.0	0.4	0.5	0.0	0.0	1.0					
Omalizumab 75mg	76	0.3	0.5	0.0	0.0	1.0	0.3	0.5	0.0	0.0	1.0					
Omalizumab 150mg	79	0.4	0.5	0.0	0.0	1.0	0.4	0.5	0.0	0.0	1.0					
Omalizumab 300mg	80	0.5	0.5	1.0	0.0	1.0	0.5	0.5	1.0	0.0	1.0					
Week 4																
Placebo	73	0.3	0.5	0.0	0.0	1.0	0.4	0.5	0.0	0.0	1.0	0.1	0.6	0.0	-1.0	1.0
Omalizumab 75mg	70	0.3	0.5	0.0	0.0	1.0	0.4	0.5	0.0	0.0	1.0	0.2	0.6	0.0	-1.0	1.0
Omalizumab 150mg	76	0.4	0.5	0.0	0.0	1.0	0.5	0.5	0.0	0.0	1.0	0.1	0.5	0.0	-1.0	1.0
Omalizumab 300mg	75	0.5	0.5	1.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.1	0.5	0.0	-1.0	1.0
Week 12																
Placebo	62	0.4	0.5	0.0	0.0	1.0	0.5	0.5	0.0	0.0	1.0	0.1	0.6	0.0	-1.0	1.0
Omalizumab 75mg	67	0.3	0.5	0.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.3	0.5	0.0	-1.0	1.0
Omalizumab 150mg	62	0.4	0.5	0.0	0.0	1.0	0.5	0.5	0.0	0.0	1.0	0.0	0.6	0.0	-1.0	1.0
Omalizumab 300mg	71	0.5	0.5	1.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.0	0.6	0.0	-1.0	1.0
Week 24																
Placebo	51	0.4	0.5	0.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.2	0.6	0.0	-1.0	1.0
Omalizumab 75mg	60	0.3	0.5	0.0	0.0	1.0	0.5	0.5	1.0	0.0	1.0	0.2	0.6	0.0	-1.0	1.0
Omalizumab 150mg	53	0.4	0.5	0.0	0.0	1.0	0.5	0.5	1.0	0.0	1.0	0.2	0.5	0.0	-1.0	1.0
Omalizumab 300mg	67	0.5	0.5	1.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.0	0.6	0.0	-1.0	1.0
Week 40																
Placebo	43	0.3	0.5	0.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.2	0.6	0.0	-1.0	1.0
Omalizumab 75mg	45	0.3	0.5	0.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	0.3	0.7	0.0	-1.0	1.0
Omalizumab 150mg	47	0.4	0.5	0.0	0.0	1.0	0.4	0.5	0.0	0.0	1.0	0.0	0.5	0.0	-1.0	1.0
Omalizumab 300mg	49	0.6	0.5	1.0	0.0	1.0	0.6	0.5	1.0	0.0	1.0	-0.0	0.6	0.0	-1.0	1.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Table 14.2/27
Mean and Mean Change from Baseline in MOS Sleep Score by Study Week (Observed Data)
Modified Intention to Treat Patients

MOS Domain: Optimal Sleep

		Baseline					Value at Visit					Change from Baseline				
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max
Early Term																
Placebo	1	0.0		0.0	0.0	0.0	1.0		1.0	1.0	1.0	1.0		1.0	1.0	1.0
Omalizumab 75mg	2	0.0	0.0	0.0	0.0	0.0	0.5	0.7	0.5	0.0	1.0	0.5	0.7	0.5	0.0	1.0
Omalizumab 150mg	4	0.5	0.6	0.5	0.0	1.0	0.0	0.0	0.0	0.0	0.0	-0.5	0.6	-0.5	-1.0	0.0
Omalizumab 300mg	4	0.5	0.6	0.5	0.0	1.0	0.5	0.6	0.5	0.0	1.0	0.0	0.0	0.0	0.0	0.0

Baseline domain scores are derived from questionnaires assessed on Day 1.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_meanchg)
Database (CLOSED) Datasets (mosseff)
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Table 14.2/19.2
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 24 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Proportion of Itch-Free Days				
n	55	63	57	70
Mean (SD)	34.9% (39.5%)	41.2% (44.2%)	43.5% (41.4%)	69.8% (40.8%)
SE	5.3%	5.6%	5.5%	4.9%
Median	14.3%	14.3%	28.6%	100.0%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(24.3%, 45.6%)	(30.1%, 52.3%)	(32.5%, 54.4%)	(60.1%, 79.6%)
Treatment Difference in LS Means* (relative to the Placebo group)		6.0%	7.6%	35.8%
95% CI of the LS Means Difference		(-9.4%, 21.4%)	(-7.8%, 22.9%)	(21.2%, 50.4%)
p-value^		0.4428	0.3303	<.0001
Change from Baseline in Proportion of Hive-Free Days				
n	55	63	57	70
Mean (SD)	38.4% (40.0%)	39.4% (42.9%)	52.3% (44.0%)	75.3% (39.1%)
SE	5.4%	5.4%	5.8%	4.7%
Median	28.6%	14.3%	57.1%	100.0%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(27.6%, 49.2%)	(28.6%, 50.2%)	(40.6%, 63.9%)	(66.0%, 84.6%)
Treatment Difference in LS Means* (relative to the Placebo group)		1.0%	14.9%	39.0%
95% CI of the LS Means Difference		(-14.2%, 16.3%)	(-1.0%, 30.9%)	(24.8%, 53.1%)
p-value^		0.8941	0.0656	<.0001
Change from Baseline in Proportion of Itch-Free and Hive-Free Days				
n	55	63	57	70
Mean (SD)	31.6% (39.3%)	37.3% (44.0%)	42.0% (42.1%)	68.4% (42.4%)

The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 24. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 24. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 24. This analysis will include only patients who have non-missing weekly itch and hive scores at Week 24. Baseline proportions of itch-free days and /or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (<median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg). ^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_wk24)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/19.2
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 24 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
SE	5.3%	5.5%	5.6%	5.1%
Median	0.0%	14.3%	28.6%	100.0%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(20.9%, 42.2%)	(26.3%, 48.4%)	(30.8%, 53.1%)	(58.3%, 78.5%)
Treatment Difference in LS Means* (relative to the Placebo group)		5.6%	9.8%	38.0%
95% CI of the LS Means Difference		(-9.8%, 20.9%)	(-5.6%, 25.3%)	(23.1%, 52.8%)
p-value^		0.4747	0.2107	<.0001

The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number days in Week 24. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 24. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 24. This analysis will include only patients who have non-missing weekly itch and hive scores at Week 24. Baseline proportions of itch-free days and /or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (<median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg). ^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_wk24)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/2.2
Change from Baseline in Weekly Itch Severity Score at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Itch Severity Score				
n	80	77	80	81
Mean (SD)	-5.41 (5.76)	-6.98 (6.42)	-6.47 (6.50)	-9.84 (5.95)
SE	0.64	0.73	0.73	0.66
Median	-4.5	-7.0	-5.5	-11.0
Range	-21.0 - 4.5	-21.0 - 4.5	-21.0 - 10.5	-19.5 - 0.0
95% CI of the Mean	(-6.69, -4.12)	(-8.44, -5.52)	(-7.91, -5.02)	(-11.15, -8.52)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.73	-1.02	-4.49
95% CI of the LS Means Difference		(-3.60, 0.13)	(-2.91, 0.86)	(-6.31, -2.68)
p-value^		0.0687	0.2860	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly itch severity score (< 13 vs. >=13), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_itch_lsmpval)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/4.2
Change from Baseline in UAS7 at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in UAS7				
n	80	77	80	81
Mean (SD)	-11.73 (12.53)	-14.92 (13.77)	-14.21 (13.33)	-22.11 (12.46)
SE	1.40	1.57	1.49	1.38
Median	-8.8	-15.0	-11.3	-25.5
Range	-42.0 - 11.5	-42.0 - 7.0	-40.0 - 10.5	-40.0 - 0.0
95% CI of the Mean	(-14.52, -8.94)	(-18.05, -11.80)	(-17.18, -11.25)	(-24.87, -19.36)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.24	-2.57	-10.47
95% CI of the LS Means Difference		(-7.40, 0.91)	(-6.63, 1.49)	(-14.41, -6.54)
p-value^		0.1254	0.2126	<.0001

BOCF = Baseline observation carried forward.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline UAS7 (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/6.2
Change from Baseline in Weekly Number of Hives Score at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Number of Hives Score				
n	80	77	80	81
Mean (SD)	-6.32 (7.24)	-7.95 (7.73)	-7.75 (7.26)	-12.28 (7.33)
SE	0.81	0.88	0.81	0.81
Median	-4.0	-7.5	-6.8	-14.0
Range	-21.0 - 7.0	-21.0 - 3.0	-21.0 - 2.5	-21.0 - 0.5
95% CI of the Mean	(-7.93, -4.71)	(-9.70, -6.19)	(-9.36, -6.13)	(-13.90, -10.66)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.51	-1.48	-5.99
95% CI of the LS Means Difference		(-3.87, 0.85)	(-3.75, 0.79)	(-8.28, -3.69)
p-value^		0.2094	0.2009	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly number of hives score (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hive_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/11.2
Change from Baseline in Weekly Size of Largest Hive Score at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Weekly Size of Largest Hive Score				
n	80	77	80	81
Mean (SD)	-5.25 (6.69)	-6.33 (7.14)	-6.81 (6.94)	-10.74 (7.00)
SE	0.75	0.81	0.78	0.78
Median	-3.8	-5.3	-6.0	-11.5
Range	-21.0 - 6.0	-21.0 - 5.5	-21.0 - 5.0	-21.0 - 2.0
95% CI of the Mean	(-6.74, -3.76)	(-7.95, -4.71)	(-8.35, -5.26)	(-12.29, -9.20)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.21	-1.71	-5.41
95% CI of the LS Means Difference		(-3.37, 0.95)	(-3.84, 0.42)	(-7.50, -3.33)
p-value^		0.2685	0.1141	<.0001

BOCF = Baseline observation carried forward.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.
* The LS mean was estimated using ANCOVA model. The strata are for baseline weekly size of largest hive score (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lghive_lsmpval)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/28.1
Patients with UAS7 <= 6 at Week 24
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 24 UAS7				
<=6	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
>6	60 (75.0%)	54 (70.1%)	51 (63.8%)	31 (38.3%)
p-value* (relative to the Placebo group)		0.4026	0.1613	<.0001

p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 24, the patient will be counted as Week 24 UAS7 > 6.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_wk24)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/53.1
Patients with Complete Response (UAS7=0) at Week 24
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Complete Response (UAS7=0)				
Yes	10 (12.5%)	18 (23.4%)	16 (20.0%)	39 (48.1%)
No	70 (87.5%)	59 (76.6%)	64 (80.0%)	42 (51.9%)
p-value* (relative to the Placebo group)		0.0654	0.2286	<.0001

* p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 24, the patient will be counted as non-responder.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_zero_wk24)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/20.2
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Proportion of Itch-Free Days				
n	80	77	80	81
Mean (SD)	24.0% (36.5%)	33.7% (43.0%)	31.0% (40.1%)	60.3% (44.9%)
SE	4.1%	4.9%	4.5%	5.0%
Median	0.0%	0.0%	0.0%	85.7%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(15.9%, 32.1%)	(23.9%, 43.5%)	(22.0%, 39.9%)	(50.4%, 70.3%)
Treatment Difference in LS Means* (relative to the Placebo group)		9.6%	6.5%	36.5%
95% CI of the LS Means Difference		(-3.0%, 22.2%)	(-5.5%, 18.5%)	(23.6%, 49.4%)
p-value^		0.1348	0.2870	<.0001
Change from Baseline in Proportion of Hive-Free Days				
n	80	77	80	81
Mean (SD)	26.4% (37.6%)	32.2% (41.7%)	37.2% (44.0%)	65.1% (44.7%)
SE	4.2%	4.7%	4.9%	5.0%
Median	0.0%	0.0%	7.1%	100.0%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(18.0%, 34.8%)	(22.8%, 41.7%)	(27.4%, 47.0%)	(55.2%, 75.0%)
Treatment Difference in LS Means* (relative to the Placebo group)		6.0%	10.9%	39.4%
95% CI of the LS Means Difference		(-6.5%, 18.6%)	(-1.9%, 23.8%)	(26.5%, 52.4%)
p-value^		0.3427	0.0944	<.0001
Change from Baseline in Proportion of Itch-Free and Hive-Free Days				
n	80	77	80	81
Mean (SD)	21.7% (35.6%)	30.6% (42.3%)	29.9% (40.3%)	59.1% (45.9%)
SE	4.0%	4.8%	4.5%	5.1%

BOCF = Baseline observation carried forward. The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number of days in Week 24. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 24. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 24. Baseline proportions of itch-free days and/or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date. * The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_bocf_wk24)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/20.2
Change from Baseline in Proportion of Itch-Free Days and/or Hive-Free Days at Week 24 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	0.0%	0.0%	0.0%	85.7%
Range	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%	0.0% - 100.0%
95% CI of the Mean	(13.8%, 29.6%)	(21.0%, 40.1%)	(20.9%, 38.9%)	(48.9%, 69.2%)
Treatment Difference in LS Means* (relative to the Placebo group)		8.8%	7.8%	37.7%
95% CI of the LS Means Difference		(-3.6%, 21.2%)	(-4.1%, 19.8%)	(24.8%, 50.6%)
p-value^		0.1623	0.1949	<.0001

BOCF = Baseline observation carried forward. The proportion of itch-free days is defined by the number of days a patient has a daily itch score of 0 over the number of days in Week 24. Similarly, the proportion of hive-free days is defined by the number of days a patient has a daily hive score of 0 over number of days in Week 24. The number of itch-free and hive-free days is defined as the number of days that both the daily itch and the daily hive score are 0 over the number of days in Week 24. Baseline proportions of itch-free days and/or hive-free days are calculated using eDiary data from the 7 days prior to the first treatment date. * The LS mean was estimated using ANCOVA model. The strata are baseline proportion or itch-free days and/or hive-free days (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_propfree_lsmpval_bocf_wk24)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 14:37 Page 2 of 2

Table 14.2/26.2
Change from Baseline in MOS Sleep Score at Week 24(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Sleep Disturbance				
n	51	60	55	69
Mean (SD)	-18.5 (25.7)	-18.8 (23.6)	-18.9 (28.7)	-24.1 (25.7)
SE	3.6	3.0	3.9	3.1
Median	-16.3	-15.0	-16.3	-25.0
Range	-93.8 - 32.5	-95.0 - 36.3	-100.0 - 57.5	-87.5 - 41.3
95% CI of the Mean	(-25.8, -11.3)	(-24.9, -12.7)	(-26.7, -11.2)	(-30.3, -18.0)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.2	-1.7	-6.4
95% CI of the LS Means Difference		(-9.0, 6.7)	(-10.6, 7.2)	(-14.6, 1.9)
p-value^		0.7696	0.7012	0.1282
Change from Baseline in Snoring				
n	51	59	55	68
Mean (SD)	-0.4 (25.1)	-2.7 (24.5)	-4.7 (28.0)	-8.5 (20.8)
SE	3.5	3.2	3.8	2.5
Median	0.0	0.0	0.0	0.0
Range	-60.0 - 60.0	-80.0 - 60.0	-100.0 - 100.0	-80.0 - 40.0
95% CI of the Mean	(-7.5, 6.7)	(-9.1, 3.7)	(-12.3, 2.8)	(-13.6, -3.5)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.8	-3.2	-6.7
95% CI of the LS Means Difference		(-10.8, 7.3)	(-13.3, 6.9)	(-14.9, 1.6)
p-value^		0.6992	0.5346	0.1108

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk24)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.2
Change from Baseline in MOS Sleep Score at Week 24(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Short of Breath				
n	51	60	55	69
Mean (SD)	0.8 (21.9)	-6.0 (25.1)	-13.8 (28.8)	-12.8 (28.3)
SE	3.1	3.2	3.9	3.4
Median	0.0	0.0	0.0	0.0
Range	-60.0 - 80.0	-60.0 - 80.0	-100.0 - 40.0	-100.0 - 40.0
95% CI of the Mean	(-5.4, 6.9)	(-12.5, 0.5)	(-21.6, -6.0)	(-19.5, -6.0)
Treatment Difference in LS Means* (relative to the Placebo group)		-3.0	-6.9	-8.5
95% CI of the LS Means Difference		(-11.1, 5.1)	(-16.0, 2.3)	(-16.6, -0.3)
p-value^		0.4657	0.1386	0.0418
Change from Baseline in Sleep Adequacy				
n	51	60	55	69
Mean (SD)	12.0 (25.3)	6.8 (25.7)	13.6 (25.7)	13.5 (34.8)
SE	3.5	3.3	3.5	4.2
Median	10.0	10.0	10.0	10.0
Range	-40.0 - 80.0	-60.0 - 70.0	-40.0 - 100.0	-80.0 - 100.0
95% CI of the Mean	(4.8, 19.1)	(0.2, 13.5)	(6.7, 20.6)	(5.1, 21.8)
Treatment Difference in LS Means* (relative to the Placebo group)		-5.9	2.0	4.5
95% CI of the LS Means Difference		(-14.5, 2.7)	(-6.7, 10.7)	(-5.7, 14.6)
p-value^		0.1787	0.6519	0.3859

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk24)
Database (CLOSED) Datasets (pat mosseff)
: Generated 25JAN13 14:34 Page 2 of 5

Table 14.2/26.2
Change from Baseline in MOS Sleep Score at Week 24(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Somnolence				
n	51	60	55	69
Mean (SD)	-9.2 (21.6)	-11.0 (25.1)	-14.7 (23.1)	-11.7 (21.2)
SE	3.0	3.2	3.1	2.5
Median	-6.7	-6.7	-13.3	-13.3
Range	-66.7 - 33.3	-80.0 - 46.7	-80.0 - 33.3	-86.7 - 40.0
95% CI of the Mean	(-15.2, -3.1)	(-17.5, -4.5)	(-20.9, -8.4)	(-16.8, -6.6)
Treatment Difference in LS Means* (relative to the Placebo group)		-1.0	-5.5	-3.1
95% CI of the LS Means Difference		(-8.8, 6.7)	(-13.1, 2.0)	(-10.4, 4.2)
p-value^		0.7898	0.1482	0.4085
Change from Baseline in Sleep Problems Index I				
n	51	60	55	69
Mean (SD)	-12.2 (20.0)	-11.7 (16.2)	-15.9 (22.0)	-16.4 (20.8)
SE	2.8	2.1	3.0	2.5
Median	-13.3	-10.0	-13.3	-13.3
Range	-83.3 - 26.7	-43.3 - 43.3	-100.0 - 40.0	-83.3 - 26.7
95% CI of the Mean	(-17.8, -6.6)	(-15.8, -7.5)	(-21.8, -9.9)	(-21.4, -11.4)
Treatment Difference in LS Means* (relative to the Placebo group)		1.2	-4.0	-3.9
95% CI of the LS Means Difference		(-5.4, 7.8)	(-11.5, 3.5)	(-10.9, 3.1)
p-value^		0.7114	0.2959	0.2710

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk24)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.2
Change from Baseline in MOS Sleep Score at Week 24(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Sleep Problems Index II				
n	51	60	55	69
Mean (SD)	-13.4 (19.5)	-13.0 (17.1)	-16.7 (22.1)	-18.5 (20.3)
SE	2.7	2.2	3.0	2.4
Median	-10.6	-11.7	-13.9	-18.3
Range	-83.9 - 20.0	-52.8 - 35.6	-100.0 - 41.1	-78.9 - 27.2
95% CI of the Mean	(-18.9, -7.9)	(-17.5, -8.6)	(-22.7, -10.7)	(-23.4, -13.6)
Treatment Difference in LS Means* (relative to the Placebo group)		0.7	-3.0	-4.5
95% CI of the LS Means Difference		(-5.9, 7.3)	(-10.4, 4.4)	(-11.4, 2.3)
p-value^		0.8315	0.4196	0.1951
Change from Baseline in Sleep Quantity				
n	51	60	53	67
Mean (SD)	0.4 (1.1)	0.5 (1.5)	0.6 (1.5)	0.2 (1.2)
SE	0.2	0.2	0.2	0.1
Median	0.0	0.0	0.0	0.0
Range	-2.0 - 2.0	-3.0 - 7.0	-2.0 - 7.0	-2.0 - 3.0
95% CI of the Mean	(0.0, 0.7)	(0.1, 0.8)	(0.2, 1.1)	(-0.0, 0.5)
Treatment Difference in LS Means* (relative to the Placebo group)		0.1	0.4	-0.1
95% CI of the LS Means Difference		(-0.4, 0.5)	(-0.1, 0.8)	(-0.5, 0.3)
p-value^		0.7830	0.1288	0.6059

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk24)
Database (CLOSED) Datasets (pat mosseff)
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Table 14.2/26.2
Change from Baseline in MOS Sleep Score at Week 24(Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Optimal Sleep				
n	51	60	53	67
Mean (SD)	0.2 (0.6)	0.2 (0.6)	0.2 (0.5)	0.0 (0.6)
SE	0.1	0.1	0.1	0.1
Median	0.0	0.0	0.0	0.0
Range	-1.0 - 1.0	-1.0 - 1.0	-1.0 - 1.0	-1.0 - 1.0
95% CI of the Mean	(0.1, 0.4)	(0.1, 0.4)	(0.0, 0.3)	(-0.1, 0.2)
Treatment Difference in LS Means* (relative to the Placebo group)		-0.0	-0.1	-0.2
95% CI of the LS Means Difference		(-0.2, 0.2)	(-0.3, 0.1)	(-0.4, 0.0)
p-value^		0.9587	0.4968	0.0527

Baseline domain scores are derived from questionnaires assessed on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for the domain score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_mos_wk24)
Database (CLOSED) Datasets (pat mosseff)
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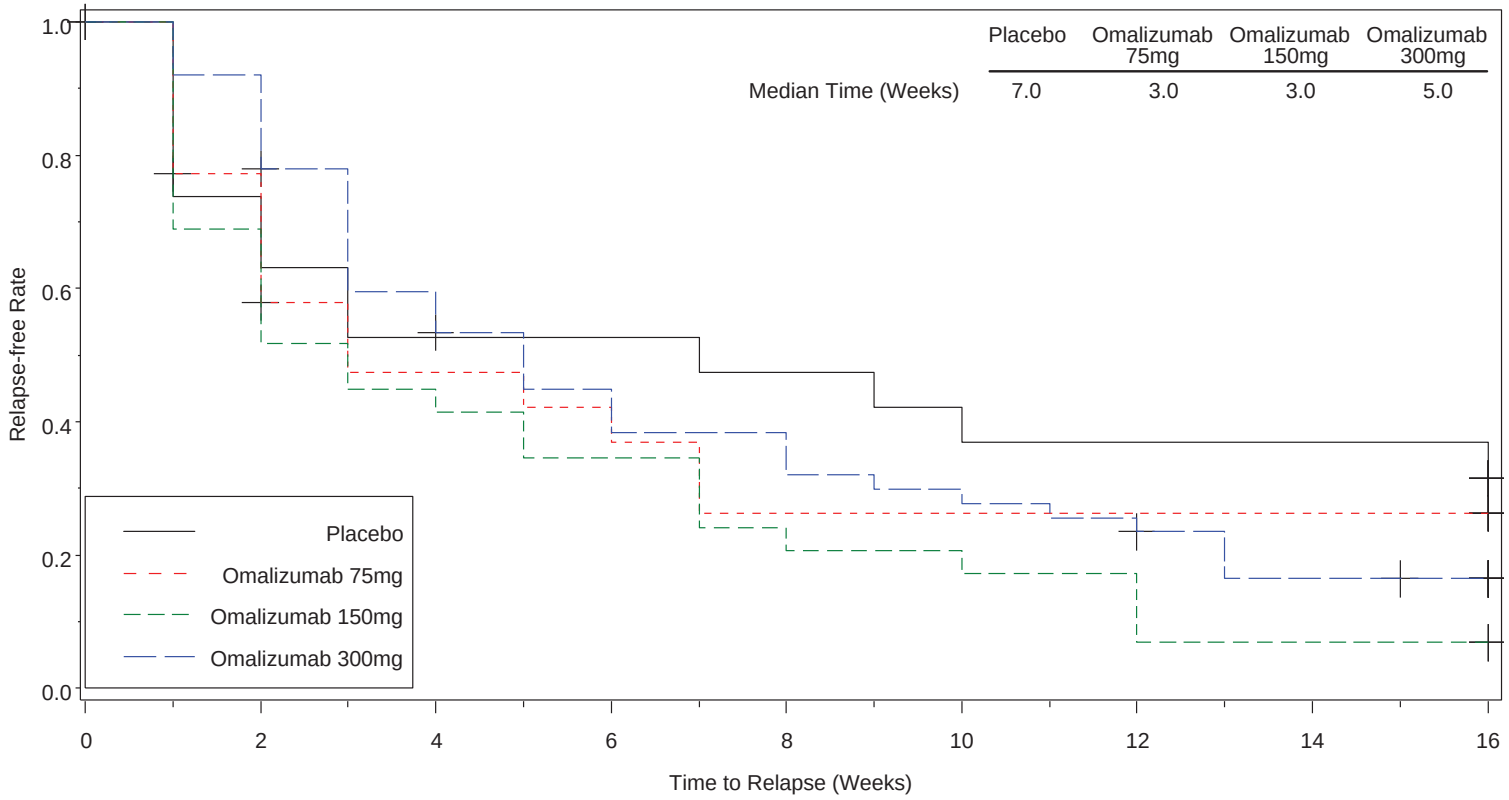
Figure 14.2/6
Time to Relapse (UAS7>6) after Week 24
Week 24 UAS7 Responders



Number of Patients at risk

Placebo	20	14	10	10	9	8	7	7	7
Omalizumab 75mg	23	16	9	8	5	5	5	5	5
Omalizumab 150mg	29	20	13	10	7	6	5	2	2
Omalizumab 300mg	50	46	29	21	18	14	12	7	6

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_uas_relapse) output (g_uas_relapse)
Database (CLOSED) Datasets (pateff)
: Generated 25JAN13 15:02 Page 1 of 1

Table 14.2/28.2
Patients with UAS7 <= 6 at Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 40 UAS7				
<=6	18 (22.5%)	12 (15.6%)	15 (18.8%)	13 (16.0%)
>6	62 (77.5%)	65 (84.4%)	65 (81.3%)	68 (84.0%)
p-value* (relative to the Placebo group)		0.2779	0.4409	0.2779

p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 40, the patient will be counted as Week 40 UAS7 > 6.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_wk40)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/29
Patients who Maintained Response (UAS7 <= 6) to Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Patients with UAS7 <= 6 at Week 24	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
Patients maintaining Response (UAS7 <= 6) from Week 24 to Week 40*	5 (6.3%)	5 (6.5%)	2 (2.5%)	6 (7.4%)

*Patients with a missing UAS7 for any week from Week 25 to Week 40 will be classified as not maintaining the response to the Week 40 visit.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_resp)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/31
Time to Relapse (UAS7>6) after Week 24
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Patients with UAS7 <= 6 at Week 24	20 (25.0%)	23 (29.9%)	29 (36.3%)	50 (61.7%)
Patients with relapse (UAS7> 6) after Week 24 response	13 (16.3%)	15 (19.5%)	27 (33.8%)	40 (49.4%)
Time to relapse (weeks) among Week 24 Responders				
Median	7.0	3.0	3.0	5.0
(95% CI)	(1.0, NE)	(2.0, 7.0)	(1.0, 7.0)	(3.0, 8.0)
25th - 75th percentile	1.0 - NE	2.0 - NE	1.0 - 7.0	3.0 - 12.0
Minimum - Maximum	0.0+ - 16.0+	0.0+ - 16.0+	1.0 - 16.0+	1.0 - 16.0+

+ = censored value.
The time to relapse analysis is restricted to patients who achieved UAS7 <= 6 at Week 24.
Summaries of time to event variable (median, percentiles, and range) are based on Kaplan-Meier estimates of the distribution of the time from the Week 24 visit to the first week where UAS7 > 6.
The 95% confidence interval (CI) for the median was computed using the method of Brookmeyer and Crowley.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_relapse)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/53.2
Patients with Complete Response (UAS7=0) at Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Complete Response (UAS7=0)				
Yes	11 (13.8%)	7 (9.1%)	9 (11.3%)	8 (9.9%)
No	69 (86.3%)	70 (90.9%)	71 (88.8%)	73 (90.1%)
p-value* (relative to the Placebo group)		0.3584	0.5343	0.4266

* p-value is derived from the Cochran Mantel Haenszel test stratified by baseline UAS7 (< median vs. >= median), and baseline weight (< 80 kg vs. >= 80 kg).
If a patient discontinued treatment before Week 40, the patient will be counted as non-responder.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_uas_zero_wk40)
Database (CLOSED) Datasets (pat pateff diaryeff)
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Table 14.2/18
Change from Baseline in Overall Dermatology Life Quality Index (DLQI) Score at Week 24 and Week 40 (Observed Data)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Overall DLQI Score at Week 24				
n	50	59	55	69
Mean (SD)	-8.1 (5.8)	-7.6 (6.6)	-8.6 (6.4)	-10.6 (7.0)
SE	0.81	0.86	0.86	0.84
Median	-7.0	-9.0	-8.0	-11.0
Range	-23.0 - 11.0	-24.0 - 15.0	-27.0 - 3.0	-27.0 - 6.0
95% CI of the Mean	(-9.74, -6.46)	(-9.29, -5.86)	(-10.33, -6.87)	(-12.26, -8.90)
Treatment Difference in LS Means* (relative to the Placebo group)		1.2	0.1	-2.0
95% CI of the LS Means Difference		(-1.0, 3.4)	(-2.0, 2.2)	(-4.0, -0.1)
p-value^		0.2885	0.9392	0.0388
Change from Baseline in Overall DLQI Score at Week 40				
n	43	45	49	50
Mean (SD)	-7.9 (8.0)	-7.0 (5.8)	-5.2 (6.7)	-4.9 (8.1)
SE	1.21	0.86	0.96	1.15
Median	-7.0	-6.0	-3.0	-5.5
Range	-27.0 - 13.0	-21.0 - 3.0	-23.0 - 7.0	-18.0 - 18.0
95% CI of the Mean	(-10.36, -5.46)	(-8.73, -5.27)	(-7.10, -3.23)	(-7.16, -2.56)
Treatment Difference in LS Means* (relative to the Placebo group)		1.7	3.1	3.4
95% CI of the LS Means Difference		(-0.9, 4.4)	(0.4, 5.9)	(0.2, 6.5)
p-value^		0.2001	0.0274	0.0351

Baseline overall DLQI score is the measurement taken prior to dosing on Day 1.
*The LS mean was estimated using ANCOVA model. The strata are for baseline overall DLQI score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.
Observed data only. No imputation for missing scores. Patients who discontinued treatment before Week 12 or Week 24 will have their scores deemed missing afterwards.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_wk2440)
Database (CLOSED) Datasets (pat dlqieff)
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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Baseline				
n	80	77	80	81
Number of patients who had angioedema^	44 (55.0%)	35 (45.5%)	38 (47.5%)	34 (42.0%)
Number of days a patient had angioedema per patient				
Mean (SD)	1.45 (1.83)	1.71 (2.43)	1.76 (2.31)	1.15 (1.77)
Median	1.0	0.0	0.0	0.0
Range	0.0 - 6.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	116	132	141	93
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.6 (1.7)	3.8 (2.3)	3.7 (2.0)	2.7 (1.8)
Median	2.0	3.0	4.0	2.0
Range	1.00 - 6.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	116.0	132.0	141.0	93.0
Angioedema management*				
Did nothing	18 (40.9%)	19 (54.3%)	20 (52.6%)	22 (64.7%)
Took some prescription or non-prescription medication	31 (70.5%)	21 (60.0%)	28 (73.7%)	17 (50.0%)
Called doctor, nurse or nurse practitioner	1 (2.3%)	1 (2.9%)	1 (2.6%)	1 (2.9%)
Went to see doctor, nurse or nurse practitioner	1 (2.3%)	2 (5.7%)	1 (2.6%)	(0.0%)
Week 1				
n	80	75	79	80
Number of patients who had angioedema^	34 (42.5%)	30 (40.0%)	33 (41.8%)	22 (27.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	1.25 (1.89)	1.22 (1.95)	1.18 (1.84)	0.69 (1.38)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 6.0
Sum	100	92	93	55
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.9 (1.9)	3.1 (2.0)	2.8 (1.9)	2.5 (1.6)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_angio)
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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	3.0	3.0	2.0	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 6.00
Sum	99.8	91.5	93.4	54.8
Angioedema management*				
Did nothing	16 (47.1%)	17 (56.7%)	16 (48.5%)	14 (63.6%)
Took some prescription or non-prescription medication	24 (70.6%)	17 (56.7%)	19 (57.6%)	11 (50.0%)
Called doctor, nurse or nurse practitioner	2 (5.9%)	3 (10.0%)	(0.0%)	1 (4.5%)
Went to see doctor, nurse or nurse practitioner	1 (2.9%)	(0.0%)	2 (6.1%)	1 (4.5%)
Week 2				
n	77	73	80	78
Number of patients who had angioedema^	31 (40.3%)	22 (30.1%)	27 (33.8%)	17 (21.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	1.00 (1.61)	0.95 (1.95)	1.00 (1.74)	0.56 (1.32)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 6.0
Sum	77	69	80	44
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.5 (1.7)	3.1 (2.4)	3.0 (1.8)	2.6 (1.7)
Median	2.0	2.2	2.0	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 6.00
Sum	77.3	69.0	79.9	43.7
Angioedema management*				
Did nothing	13 (41.9%)	9 (40.9%)	15 (55.6%)	8 (47.1%)
Took some prescription or non-prescription medication	19 (61.3%)	13 (59.1%)	16 (59.3%)	12 (70.6%)
Called doctor, nurse or nurse practitioner	3 (9.7%)	1 (4.5%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (5.9%)
Week 3				
n	75	73	79	77

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of patients who had angioedema^	26 (34.7%)	23 (31.5%)	22 (27.8%)	14 (18.2%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.88 (1.56)	0.96 (1.78)	1.00 (1.90)	0.52 (1.35)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	66	70	79	40
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.5 (1.7)	3.0 (1.9)	3.6 (1.9)	2.8 (1.9)
Median	2.0	3.0	4.0	2.5
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	66.1	70.0	79.3	39.7
Angioedema management*				
Did nothing	15 (57.7%)	11 (47.8%)	10 (45.5%)	7 (50.0%)
Took some prescription or non-prescription medication	15 (57.7%)	13 (56.5%)	15 (68.2%)	9 (64.3%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (4.5%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (4.5%)	(0.0%)
Week 4				
n	72	71	75	76
Number of patients who had angioedema^	28 (38.9%)	25 (35.2%)	27 (36.0%)	12 (15.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	1.12 (1.89)	1.30 (2.16)	0.98 (1.72)	0.52 (1.36)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 6.0
Sum	81	92	73	39
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.9 (2.0)	3.7 (2.1)	2.7 (1.9)	3.3 (1.7)
Median	2.3	3.0	2.0	2.9
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 6.00

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Sum	80.7	92.3	73.2	39.3
Angioedema management*				
Did nothing	13 (46.4%)	10 (40.0%)	10 (37.0%)	6 (50.0%)
Took some prescription or non-prescription medication	19 (67.9%)	17 (68.0%)	19 (70.4%)	7 (58.3%)
Called doctor, nurse or nurse practitioner	1 (3.6%)	(0.0%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	1 (3.6%)	1 (4.0%)	2 (7.4%)	(0.0%)
Week 5				
n	65	63	69	73
Number of patients who had angioedema^	26 (40.0%)	16 (25.4%)	21 (30.4%)	9 (12.3%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.86 (1.44)	1.02 (2.15)	0.90 (1.78)	0.31 (0.96)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 5.0
Sum	56	65	62	23
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.2 (1.5)	4.0 (2.5)	3.0 (2.1)	2.5 (1.4)
Median	2.0	3.3	2.0	3.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 5.00
Sum	56.2	64.5	62.1	22.6
Angioedema management*				
Did nothing	14 (53.8%)	10 (62.5%)	9 (42.9%)	1 (11.1%)
Took some prescription or non-prescription medication	14 (53.8%)	7 (43.8%)	12 (57.1%)	8 (88.9%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	2 (9.5%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	1 (3.8%)	(0.0%)	1 (4.8%)	(0.0%)
Week 6				
n	70	70	74	73
Number of patients who had angioedema^	20 (28.6%)	17 (24.3%)	24 (32.4%)	7 (9.6%)
Number of days a patient had angioedema per patient				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	0.88 (1.76)	0.93 (2.04)	0.99 (1.81)	0.21 (0.76)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 5.0
Sum	61	65	73	15
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	3.1 (2.0)	3.8 (2.5)	3.0 (2.0)	2.1 (1.5)
Median	2.2	3.0	2.7	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 5.00
Sum	61.5	65.2	73.2	15.0
Angioedema management*				
Did nothing	11 (55.0%)	9 (52.9%)	10 (41.7%)	3 (42.9%)
Took some prescription or non-prescription medication	11 (55.0%)	8 (47.1%)	16 (66.7%)	6 (85.7%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (4.2%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (4.2%)	(0.0%)
Week 7				
n	68	72	72	76
Number of patients who had angioedema^	17 (25.0%)	19 (26.4%)	14 (19.4%)	9 (11.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.74 (1.66)	1.05 (2.24)	0.65 (1.60)	0.28 (0.95)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 6.0
Sum	50	76	47	21
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.9 (2.1)	4.0 (2.7)	3.3 (2.1)	2.4 (1.7)
Median	2.3	4.7	2.7	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 6.00
Sum	50.1	75.7	46.7	21.2
Angioedema management*				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Did nothing	10 (58.8%)	9 (47.4%)	7 (50.0%)	2 (22.2%)
Took some prescription or non-prescription medication	8 (47.1%)	11 (57.9%)	9 (64.3%)	8 (88.9%)
Called doctor, nurse or nurse practitioner	(0.0%)	1 (5.3%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	1 (5.3%)	1 (7.1%)	(0.0%)
Week 8				
n	67	66	69	71
Number of patients who had angioedema^	24 (35.8%)	19 (28.8%)	18 (26.1%)	11 (15.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.90 (1.59)	0.99 (2.08)	0.73 (1.48)	0.43 (1.22)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	60	66	50	30
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.5 (1.7)	3.5 (2.6)	2.8 (1.7)	2.8 (1.8)
Median	2.0	2.0	2.9	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	60.3	65.6	50.0	30.3
Angioedema management*				
Did nothing	16 (66.7%)	7 (36.8%)	10 (55.6%)	4 (36.4%)
Took some prescription or non-prescription medication	9 (37.5%)	12 (63.2%)	9 (50.0%)	9 (81.8%)
Called doctor, nurse or nurse practitioner	2 (8.3%)	(0.0%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	2 (11.1%)	(0.0%)
Week 9				
n	60	61	60	66
Number of patients who had angioedema^	18 (30.0%)	17 (27.9%)	9 (15.0%)	10 (15.2%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.94 (1.79)	1.12 (2.28)	0.33 (0.99)	0.27 (0.68)
Median	0.0	0.0	0.0	0.0

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 5.0	0.0 - 3.0
Sum	56	68	20	18
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	3.1 (2.0)	4.0 (2.7)	2.2 (1.6)	1.8 (0.6)
Median	2.6	4.0	1.4	1.9
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 5.00	1.00 - 3.00
Sum	56.2	68.2	20.1	17.8
Angioedema management*				
Did nothing	11 (61.1%)	7 (41.2%)	5 (55.6%)	5 (50.0%)
Took some prescription or non-prescription medication	9 (50.0%)	10 (58.8%)	4 (44.4%)	6 (60.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (11.1%)	(0.0%)
Week 10				
n	64	67	66	73
Number of patients who had angioedema^	15 (23.4%)	15 (22.4%)	12 (18.2%)	6 (8.2%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.77 (1.65)	0.94 (2.06)	0.44 (1.18)	0.20 (0.80)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 6.0	0.0 - 5.0
Sum	49	63	29	14
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	3.3 (1.9)	4.2 (2.3)	2.4 (1.7)	2.4 (1.7)
Median	3.0	4.0	1.7	1.6
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 6.00	1.00 - 5.00
Sum	49.0	63.1	29.1	14.3
Angioedema management*				
Did nothing	7 (46.7%)	10 (66.7%)	7 (58.3%)	2 (33.3%)
Took some prescription or non-prescription medication	11 (73.3%)	8 (53.3%)	6 (50.0%)	4 (66.7%)
Called doctor, nurse or nurse practitioner	2 (13.3%)	(0.0%)	(0.0%)	(0.0%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Went to see doctor, nurse or nurse practitioner	1 (6.7%)	(0.0%)	(0.0%)	(0.0%)
Week 11				
n	64	65	66	72
Number of patients who had angioedema^	21 (32.8%)	16 (24.6%)	10 (15.2%)	5 (6.9%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.90 (1.64)	0.93 (2.01)	0.43 (1.28)	0.19 (0.76)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 5.0
Sum	57	61	28	14
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.7 (1.8)	3.8 (2.4)	2.8 (2.1)	2.7 (1.3)
Median	2.3	3.7	2.2	2.3
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	2.00 - 5.00
Sum	57.3	60.6	28.2	13.7
Angioedema management*				
Did nothing	12 (57.1%)	8 (50.0%)	4 (40.0%)	1 (20.0%)
Took some prescription or non-prescription medication	9 (42.9%)	9 (56.3%)	7 (70.0%)	5 (100.0%)
Called doctor, nurse or nurse practitioner	2 (9.5%)	1 (6.3%)	(0.0%)	1 (20.0%)
Week 12				
n	64	65	62	72
Number of patients who had angioedema^	17 (26.6%)	14 (21.5%)	10 (16.1%)	9 (12.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.76 (1.58)	0.88 (2.01)	0.58 (1.64)	0.33 (1.01)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 5.3
Sum	49	58	36	23
Number of days a patient had angioedema per patient (patients with angioedema)				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	2.9 (1.8)	4.1 (2.4)	3.6 (2.4)	2.6 (1.5)
Median	3.0	4.3	3.0	2.0
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 5.25
Sum	48.7	57.5	36.2	23.4
Angioedema management*				
Did nothing	10 (58.8%)	8 (57.1%)	6 (60.0%)	2 (22.2%)
Took some prescription or non-prescription medication	8 (47.1%)	7 (50.0%)	6 (60.0%)	7 (77.8%)
Went to see doctor, nurse or nurse practitioner	2 (11.8%)	(0.0%)	(0.0%)	(0.0%)
Week 13				
n	49	57	56	66
Number of patients who had angioedema^	11 (22.4%)	14 (24.6%)	10 (17.9%)	6 (9.1%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.52 (1.29)	1.17 (2.38)	0.44 (1.13)	0.22 (0.85)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 6.0	0.0 - 7.0	0.0 - 5.8	0.0 - 5.0
Sum	26	67	25	15
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.3 (1.8)	4.8 (2.4)	2.5 (1.5)	2.4 (1.7)
Median	2.0	5.5	2.0	1.7
Range	1.00 - 6.00	1.00 - 7.00	1.00 - 5.83	1.00 - 5.00
Sum	25.5	66.8	24.6	14.6
Angioedema management*				
Did nothing	7 (63.6%)	10 (71.4%)	7 (70.0%)	2 (33.3%)
Took some prescription or non-prescription medication	4 (36.4%)	9 (64.3%)	5 (50.0%)	5 (83.3%)
Week 14				
n	59	65	63	69
Number of patients who had angioedema^	17 (28.8%)	15 (23.1%)	10 (15.9%)	9 (13.0%)
Number of days a patient had angioedema per patient				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Mean (SD)	0.72 (1.40)	1.01 (2.18)	0.37 (1.07)	0.28 (0.87)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 6.0	0.0 - 7.0	0.0 - 5.6	0.0 - 5.0
Sum	42	65	24	19
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.5 (1.6)	4.4 (2.5)	2.4 (1.6)	2.1 (1.4)
Median	2.0	4.0	2.0	1.2
Range	1.00 - 6.00	1.00 - 7.00	1.00 - 5.60	1.00 - 5.00
Sum	42.3	65.3	23.6	19.2
Angioedema management*				
Did nothing	9 (52.9%)	9 (60.0%)	7 (70.0%)	5 (55.6%)
Took some prescription or non-prescription medication	8 (47.1%)	10 (66.7%)	4 (40.0%)	6 (66.7%)
Called doctor, nurse or nurse practitioner	1 (5.9%)	(0.0%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	3 (17.6%)	(0.0%)	(0.0%)	(0.0%)
Week 15				
n	57	65	63	70
Number of patients who had angioedema^	14 (24.6%)	16 (24.6%)	13 (20.6%)	8 (11.4%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.65 (1.41)	1.24 (2.46)	0.57 (1.42)	0.19 (0.58)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 6.0	0.0 - 7.0	0.0 - 7.0	0.0 - 3.0
Sum	37	80	36	14
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.6 (1.7)	5.0 (2.3)	2.8 (2.0)	1.7 (0.7)
Median	2.0	6.0	2.0	1.6
Range	1.00 - 6.00	1.00 - 7.00	1.00 - 7.00	1.00 - 3.00
Sum	36.9	80.5	36.0	13.5
Angioedema management*				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Did nothing	7 (50.0%)	10 (62.5%)	7 (53.8%)	3 (37.5%)
Took some prescription or non-prescription medication	7 (50.0%)	9 (56.3%)	8 (61.5%)	5 (62.5%)
Went to see doctor, nurse or nurse practitioner	1 (7.1%)	(0.0%)	(0.0%)	(0.0%)
Week 16				
n	59	65	58	70
Number of patients who had angioedema^	12 (20.3%)	18 (27.7%)	8 (13.8%)	9 (12.9%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.50 (1.22)	1.37 (2.59)	0.35 (1.14)	0.30 (0.89)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.8	0.0 - 7.0	0.0 - 7.0	0.0 - 5.0
Sum	29	89	21	21
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.4 (1.6)	5.0 (2.5)	2.6 (2.0)	2.3 (1.3)
Median	1.9	6.5	2.0	2.0
Range	1.00 - 5.83	1.00 - 7.00	1.00 - 7.00	1.00 - 5.00
Sum	29.3	89.4	20.5	20.7
Angioedema management*				
Did nothing	7 (58.3%)	9 (50.0%)	4 (50.0%)	4 (44.4%)
Took some prescription or non-prescription medication	5 (41.7%)	12 (66.7%)	5 (62.5%)	7 (77.8%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (11.1%)
Week 17				
n	53	56	56	63
Number of patients who had angioedema^	10 (18.9%)	12 (21.4%)	5 (8.9%)	2 (3.2%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.48 (1.15)	1.02 (2.33)	0.25 (0.86)	0.11 (0.61)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.3	0.0 - 7.0	0.0 - 4.0	0.0 - 4.0
Sum	25	57	14	7

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.5 (1.4)	4.8 (2.8)	2.8 (1.0)	3.4 (0.8)
Median	2.2	6.4	3.0	3.4
Range	1.17 - 5.25	1.00 - 7.00	1.40 - 4.00	2.80 - 4.00
Sum	25.2	57.2	14.2	6.8
Angioedema management*				
Did nothing	6 (60.0%)	6 (50.0%)	2 (40.0%)	(0.0%)
Took some prescription or non-prescription medication	5 (50.0%)	7 (58.3%)	3 (60.0%)	2 (100.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	2 (40.0%)	(0.0%)
Week 18				
n	57	64	61	70
Number of patients who had angioedema^	13 (22.8%)	17 (26.6%)	3 (4.9%)	6 (8.6%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.52 (1.12)	1.21 (2.41)	0.15 (0.82)	0.10 (0.37)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.0	0.0 - 7.0	0.0 - 6.0	0.0 - 2.3
Sum	30	78	9	7
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.3 (1.2)	4.6 (2.6)	3.1 (2.5)	1.2 (0.5)
Median	2.0	5.0	2.0	1.0
Range	1.00 - 5.00	1.00 - 7.00	1.40 - 6.00	1.00 - 2.33
Sum	29.6	77.6	9.4	7.3
Angioedema management*				
Did nothing	8 (61.5%)	7 (41.2%)	(0.0%)	3 (50.0%)
Took some prescription or non-prescription medication	5 (38.5%)	11 (64.7%)	3 (100.0%)	3 (50.0%)
Week 19				
n	57	61	60	69

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of patients who had angioedema^	11 (19.3%)	16 (26.2%)	4 (6.7%)	6 (8.7%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.51 (1.37)	1.20 (2.37)	0.18 (0.95)	0.20 (0.92)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	29	73	11	14
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.7 (2.1)	4.6 (2.4)	2.8 (2.9)	2.3 (2.3)
Median	2.0	5.1	1.5	1.5
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	29.2	73.4	11.0	14.0
Angioedema management*				
Did nothing	6 (54.5%)	9 (56.3%)	3 (75.0%)	2 (33.3%)
Took some prescription or non-prescription medication	5 (45.5%)	8 (50.0%)	1 (25.0%)	4 (66.7%)
Called doctor, nurse or nurse practitioner	1 (9.1%)	(0.0%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	1 (9.1%)	2 (12.5%)	(0.0%)	(0.0%)
Week 20				
n	53	58	58	67
Number of patients who had angioedema^	8 (15.1%)	16 (27.6%)	7 (12.1%)	2 (3.0%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.36 (1.12)	1.26 (2.45)	0.32 (1.15)	0.13 (0.89)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.8	0.0 - 7.0	0.0 - 6.0	0.0 - 7.0
Sum	19	73	19	9
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.4 (1.9)	4.6 (2.6)	2.7 (2.2)	4.5 (3.5)
Median	1.7	5.0	2.0	4.5
Range	1.00 - 5.83	1.00 - 7.00	1.00 - 6.00	2.00 - 7.00

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Sum	19.2	73.0	18.8	9.0
Angioedema management*				
Did nothing	3 (37.5%)	8 (50.0%)	2 (28.6%)	(0.0%)
Took some prescription or non-prescription medication	5 (62.5%)	9 (56.3%)	6 (85.7%)	2 (100.0%)
Called doctor, nurse or nurse practitioner	1 (12.5%)	(0.0%)	(0.0%)	(0.0%)
Week 21				
n	48	58	52	66
Number of patients who had angioedema^	9 (18.8%)	14 (24.1%)	6 (11.5%)	2 (3.0%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.39 (0.92)	1.07 (2.35)	0.40 (1.37)	0.05 (0.31)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 7.0	0.0 - 7.0	0.0 - 2.3
Sum	19	62	21	3
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.1 (1.0)	4.4 (2.9)	3.5 (2.5)	1.7 (0.9)
Median	1.8	6.1	2.9	1.7
Range	1.00 - 3.50	1.00 - 7.00	1.00 - 7.00	1.00 - 2.33
Sum	18.6	62.0	20.8	3.3
Angioedema management*				
Did nothing	5 (55.6%)	6 (42.9%)	3 (50.0%)	(0.0%)
Took some prescription or non-prescription medication	4 (44.4%)	8 (57.1%)	4 (66.7%)	2 (100.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	1 (7.1%)	1 (16.7%)	(0.0%)
Went to the emergency room at the hospital	(0.0%)	1 (7.1%)	(0.0%)	(0.0%)
Week 22				
n	55	62	58	69
Number of patients who had angioedema^	9 (16.4%)	15 (24.2%)	4 (6.9%)	4 (5.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.38 (1.01)	1.03 (2.21)	0.34 (1.43)	0.11 (0.48)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.0	0.0 - 7.0	0.0 - 7.0	0.0 - 3.0
Sum	21	64	20	7
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.4 (1.3)	4.2 (2.6)	5.0 (2.8)	1.8 (1.0)
Median	2.0	4.0	6.0	1.7
Range	1.00 - 5.00	1.00 - 7.00	1.00 - 7.00	1.00 - 3.00
Sum	21.2	63.7	20.0	7.3
Angioedema management*				
Did nothing	5 (55.6%)	7 (46.7%)	2 (50.0%)	1 (25.0%)
Took some prescription or non-prescription medication	4 (44.4%)	10 (66.7%)	3 (75.0%)	3 (75.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (25.0%)
Week 23				
n	55	63	54	67
Number of patients who had angioedema^	10 (18.2%)	15 (23.8%)	5 (9.3%)	3 (4.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.40 (1.11)	1.15 (2.42)	0.23 (0.80)	0.10 (0.51)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 6.0	0.0 - 7.0	0.0 - 4.0	0.0 - 3.0
Sum	22	73	13	7
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.2 (1.7)	4.8 (2.6)	2.5 (1.1)	2.3 (1.0)
Median	1.7	7.0	2.3	2.8
Range	1.00 - 6.00	1.00 - 7.00	1.00 - 4.00	1.17 - 3.00
Sum	22.2	72.7	12.7	7.0
Angioedema management*				
Did nothing	5 (50.0%)	8 (53.3%)	3 (60.0%)	(0.0%)
Took some prescription or non-prescription medication	5 (50.0%)	10 (66.7%)	2 (40.0%)	3 (100.0%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Called doctor, nurse or nurse practitioner	1 (10.0%)	(0.0%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	1 (10.0%)	(0.0%)	(0.0%)	(0.0%)
Week 24				
n	54	62	55	67
Number of patients who had angioedema^	6 (11.1%)	17 (27.4%)	5 (9.1%)	5 (7.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.27 (0.86)	1.16 (2.22)	0.24 (0.90)	0.21 (1.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 4.7	0.0 - 7.0	0.0 - 5.0	0.0 - 7.0
Sum	14	72	13	14
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.4 (1.3)	4.2 (2.2)	2.6 (1.8)	2.8 (2.7)
Median	2.2	3.5	2.0	1.2
Range	1.00 - 4.67	1.00 - 7.00	1.00 - 5.00	1.00 - 7.00
Sum	14.4	71.9	13.2	14.2
Angioedema management*				
Did nothing	3 (50.0%)	8 (47.1%)	(0.0%)	1 (20.0%)
Took some prescription or non-prescription medication	3 (50.0%)	11 (64.7%)	5 (100.0%)	4 (80.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	2 (40.0%)
Went to the emergency room at the hospital	1 (16.7%)	(0.0%)	(0.0%)	(0.0%)
Week 25				
n	50	59	53	68
Number of patients who had angioedema^	8 (16.0%)	18 (30.5%)	8 (15.1%)	7 (10.3%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.55 (1.57)	1.41 (2.51)	0.60 (1.74)	0.40 (1.39)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	28	83	32	27

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	3.5 (2.4)	4.6 (2.4)	4.0 (2.6)	3.9 (2.4)
Median	2.9	5.9	3.0	3.5
Range	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	27.7	83.1	32.0	27.1
Angioedema management*				
Did nothing	6 (75.0%)	9 (50.0%)	2 (25.0%)	3 (42.9%)
Took some prescription or non-prescription medication	2 (25.0%)	10 (55.6%)	6 (75.0%)	5 (71.4%)
Called doctor, nurse or nurse practitioner	(0.0%)	1 (5.6%)	1 (12.5%)	1 (14.3%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (12.5%)	1 (14.3%)
Week 26				
n	47	60	53	70
Number of patients who had angioedema^	10 (21.3%)	20 (33.3%)	9 (17.0%)	6 (8.6%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.43 (1.03)	1.47 (2.61)	0.57 (1.43)	0.22 (0.86)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.0	0.0 - 7.0	0.0 - 6.0	0.0 - 5.3
Sum	20	88	30	15
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.0 (1.4)	4.4 (2.8)	3.4 (1.7)	2.5 (1.8)
Median	1.2	5.3	3.5	2.0
Range	1.00 - 5.00	1.00 - 7.00	1.00 - 6.00	1.00 - 5.25
Sum	20.0	88.0	30.2	15.2
Angioedema management*				
Did nothing	7 (70.0%)	11 (55.0%)	4 (44.4%)	1 (16.7%)
Took some prescription or non-prescription medication	3 (30.0%)	12 (60.0%)	7 (77.8%)	5 (83.3%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (11.1%)	1 (16.7%)
Went to see doctor, nurse or nurse practitioner	1 (10.0%)	(0.0%)	(0.0%)	(0.0%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 27				
n	48	59	51	67
Number of patients who had angioedema^	8 (16.7%)	22 (37.3%)	7 (13.7%)	9 (13.4%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.32 (1.08)	1.70 (2.63)	0.45 (1.36)	0.37 (1.09)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0	0.0 - 5.8
Sum	15	100	23	25
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.9 (2.1)	4.6 (2.4)	3.3 (2.1)	2.8 (1.5)
Median	1.2	4.3	2.0	3.0
Range	1.00 - 7.00	1.00 - 7.00	1.17 - 7.00	1.00 - 5.83
Sum	15.4	100.2	23.2	24.8
Angioedema management*				
Did nothing	3 (37.5%)	9 (40.9%)	2 (28.6%)	4 (44.4%)
Took some prescription or non-prescription medication	4 (50.0%)	16 (72.7%)	6 (85.7%)	7 (77.8%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (11.1%)
Went to see doctor, nurse or nurse practitioner	1 (12.5%)	(0.0%)	(0.0%)	(0.0%)
Week 28				
n	48	55	49	64
Number of patients who had angioedema^	5 (10.4%)	21 (38.2%)	9 (18.4%)	8 (12.5%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.28 (0.96)	1.60 (2.57)	0.53 (1.53)	0.38 (1.30)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.3	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	13	88	26	24
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.6 (1.7)	4.2 (2.5)	2.9 (2.5)	3.0 (2.5)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	2.8	5.0	2.0	1.7
Range	1.00 - 5.25	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	13.2	88.2	26.0	24.1
Angioedema management*				
Did nothing	3 (60.0%)	10 (47.6%)	3 (33.3%)	3 (37.5%)
Took some prescription or non-prescription medication	3 (60.0%)	14 (66.7%)	7 (77.8%)	6 (75.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (11.1%)	1 (12.5%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (11.1%)	1 (12.5%)
Week 29				
n	44	56	49	64
Number of patients who had angioedema^	8 (18.2%)	20 (35.7%)	9 (18.4%)	9 (14.1%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.35 (0.82)	1.49 (2.52)	0.55 (1.52)	0.32 (1.10)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	16	83	27	20
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.9 (0.8)	4.2 (2.6)	3.0 (2.4)	2.2 (2.2)
Median	2.0	4.1	2.0	1.0
Range	1.00 - 3.50	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	15.6	83.2	26.8	20.2
Angioedema management*				
Did nothing	2 (25.0%)	9 (45.0%)	4 (44.4%)	3 (33.3%)
Took some prescription or non-prescription medication	6 (75.0%)	13 (65.0%)	5 (55.6%)	7 (77.8%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	1 (5.0%)	(0.0%)	(0.0%)
Week 30				
n	45	53	49	60
Number of patients who had angioedema^	6 (13.3%)	15 (28.3%)	8 (16.3%)	7 (11.7%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of days a patient had angioedema per patient				
Mean (SD)	0.23 (0.62)	1.21 (2.41)	0.47 (1.34)	0.37 (1.28)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 2.3	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	10	64	23	22
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.7 (0.6)	4.3 (2.8)	2.9 (2.1)	3.1 (2.4)
Median	2.0	4.0	2.5	2.0
Range	1.00 - 2.33	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	10.3	64.0	23.2	22.0
Angioedema management*				
Did nothing	3 (50.0%)	6 (40.0%)	4 (50.0%)	2 (28.6%)
Took some prescription or non-prescription medication	3 (50.0%)	10 (66.7%)	5 (62.5%)	5 (71.4%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (14.3%)
Week 31				
n	45	51	50	59
Number of patients who had angioedema^	4 (8.9%)	15 (29.4%)	6 (12.0%)	7 (11.9%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.26 (0.95)	1.37 (2.54)	0.53 (1.64)	0.37 (1.21)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	12	70	27	22
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.9 (1.7)	4.7 (2.6)	4.4 (2.3)	3.1 (2.0)
Median	2.8	5.8	4.3	2.8
Range	1.17 - 5.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	11.7	69.9	26.7	22.0
Angioedema management*				

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Did nothing	3 (75.0%)	6 (40.0%)	3 (50.0%)	1 (14.3%)
Took some prescription or non-prescription medication	2 (50.0%)	11 (73.3%)	5 (83.3%)	7 (100.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	1 (6.7%)	(0.0%)	(0.0%)
Was hospitalized	(0.0%)	(0.0%)	(0.0%)	1 (14.3%)
Week 32				
n	45	49	48	57
Number of patients who had angioedema^	6 (13.3%)	13 (26.5%)	11 (22.9%)	9 (15.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.27 (0.80)	1.35 (2.54)	0.63 (1.66)	0.53 (1.53)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 4.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	12	66	30	30
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.0 (1.2)	5.1 (2.3)	2.8 (2.5)	3.4 (2.4)
Median	1.6	6.0	1.4	2.3
Range	1.00 - 4.00	1.00 - 7.00	1.00 - 7.00	1.17 - 7.00
Sum	12.0	66.3	30.4	30.3
Angioedema management*				
Did nothing	4 (66.7%)	6 (46.2%)	6 (54.5%)	1 (11.1%)
Took some prescription or non-prescription medication	3 (50.0%)	9 (69.2%)	5 (45.5%)	9 (100.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (11.1%)
Week 33				
n	44	48	48	55
Number of patients who had angioedema^	6 (13.6%)	15 (31.3%)	10 (20.8%)	9 (16.4%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.24 (0.69)	1.46 (2.58)	0.77 (1.66)	0.48 (1.44)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Sum	11	70	37	27
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.8 (1.0)	4.7 (2.5)	3.7 (1.5)	3.0 (2.4)
Median	1.5	6.0	4.0	2.0
Range	1.00 - 3.50	1.00 - 7.00	2.00 - 7.00	1.00 - 7.00
Sum	10.5	70.0	37.2	26.6
Angioedema management*				
Did nothing	3 (50.0%)	6 (40.0%)	3 (30.0%)	1 (11.1%)
Took some prescription or non-prescription medication	5 (83.3%)	12 (80.0%)	8 (80.0%)	8 (88.9%)
Called doctor, nurse or nurse practitioner	(0.0%)	1 (6.7%)	(0.0%)	1 (11.1%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (10.0%)	(0.0%)
Week 34				
n	43	47	50	54
Number of patients who had angioedema^	4 (9.3%)	14 (29.8%)	10 (20.0%)	7 (13.0%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.19 (0.66)	1.28 (2.46)	0.65 (1.65)	0.33 (1.15)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	8	60	33	18
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.0 (1.2)	4.3 (2.8)	3.3 (2.3)	2.5 (2.3)
Median	2.0	4.5	3.0	1.2
Range	1.00 - 3.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	8.0	60.0	32.6	17.7
Angioedema management*				
Did nothing	1 (25.0%)	5 (35.7%)	5 (50.0%)	2 (28.6%)
Took some prescription or non-prescription medication	3 (75.0%)	10 (71.4%)	6 (60.0%)	5 (71.4%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (14.3%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 35				
n	45	46	49	54
Number of patients who had angioedema^	4 (8.9%)	16 (34.8%)	7 (14.3%)	8 (14.8%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.18 (0.68)	1.54 (2.64)	0.59 (1.68)	0.44 (1.28)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 4.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	8	71	29	24
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.0 (1.3)	4.4 (2.7)	4.1 (2.3)	3.0 (2.0)
Median	1.5	5.4	5.0	2.0
Range	1.17 - 4.00	1.00 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	8.1	70.8	29.0	23.7
Angioedema management*				
Did nothing	2 (50.0%)	6 (37.5%)	2 (28.6%)	2 (25.0%)
Took some prescription or non-prescription medication	2 (50.0%)	13 (81.3%)	6 (85.7%)	7 (87.5%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (12.5%)
Went to the emergency room at the hospital	(0.0%)	1 (6.3%)	(0.0%)	(0.0%)
Week 36				
n	46	47	49	52
Number of patients who had angioedema^	7 (15.2%)	15 (31.9%)	5 (10.2%)	10 (19.2%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.27 (0.74)	1.39 (2.54)	0.41 (1.43)	0.60 (1.56)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	12	66	20	31
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.8 (1.0)	4.4 (2.7)	4.0 (2.5)	3.1 (2.3)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Median	1.4	6.0	4.0	2.5
Range	1.00 - 3.50	1.00 - 7.00	1.17 - 7.00	1.00 - 7.00
Sum	12.5	65.5	20.2	31.2
Angioedema management*				
Did nothing	3 (42.9%)	5 (33.3%)	2 (40.0%)	3 (30.0%)
Took some prescription or non-prescription medication	5 (71.4%)	11 (73.3%)	4 (80.0%)	8 (80.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (10.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (10.0%)
Week 37				
n	43	50	50	50
Number of patients who had angioedema^	3 (7.0%)	14 (28.0%)	8 (16.0%)	4 (8.0%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.14 (0.64)	1.39 (2.51)	0.45 (1.38)	0.32 (1.27)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 4.0	0.0 - 7.0	0.0 - 7.0	0.0 - 7.0
Sum	6	70	23	16
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.0 (1.7)	5.0 (2.1)	2.8 (2.4)	4.0 (2.6)
Median	1.0	5.5	1.7	4.0
Range	1.00 - 4.00	1.17 - 7.00	1.00 - 7.00	1.00 - 7.00
Sum	6.0	69.7	22.6	16.0
Angioedema management*				
Did nothing	(0.0%)	6 (42.9%)	4 (50.0%)	(0.0%)
Took some prescription or non-prescription medication	3 (100.0%)	9 (64.3%)	4 (50.0%)	4 (100.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	1 (7.1%)	(0.0%)	1 (25.0%)
Went to see doctor, nurse or nurse practitioner	(0.0%)	1 (7.1%)	(0.0%)	(0.0%)
Week 38				
n	43	46	49	51

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Number of patients who had angioedema^	5 (11.6%)	14 (30.4%)	6 (12.2%)	7 (13.7%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.26 (0.78)	1.34 (2.50)	0.29 (1.00)	0.20 (0.54)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 7.0	0.0 - 6.0	0.0 - 2.0
Sum	11	62	14	10
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.2 (1.0)	4.4 (2.6)	2.4 (1.9)	1.5 (0.5)
Median	1.8	5.7	1.7	1.2
Range	1.00 - 3.50	1.00 - 7.00	1.00 - 6.00	1.00 - 2.00
Sum	11.0	61.8	14.4	10.2
Angioedema management*				
Did nothing	2 (40.0%)	6 (42.9%)	2 (33.3%)	1 (14.3%)
Took some prescription or non-prescription medication	3 (60.0%)	9 (64.3%)	4 (66.7%)	6 (85.7%)
Called doctor, nurse or nurse practitioner	(0.0%)	2 (14.3%)	(0.0%)	(0.0%)
Went to see doctor, nurse or nurse practitioner	1 (20.0%)	(0.0%)	(0.0%)	(0.0%)
Went to the emergency room at the hospital	1 (20.0%)	(0.0%)	(0.0%)	(0.0%)
Week 39				
n	44	45	48	48
Number of patients who had angioedema^	4 (9.1%)	9 (20.0%)	6 (12.5%)	5 (10.4%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.21 (0.75)	1.20 (2.57)	0.37 (1.11)	0.33 (1.23)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 4.0	0.0 - 7.0	0.0 - 4.7	0.0 - 6.0
Sum	9	54	18	16
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	2.3 (1.2)	6.0 (2.0)	2.9 (1.6)	3.2 (2.5)
Median	2.2	7.0	3.5	2.0

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/34
Angioedema Management
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Range	1.00 - 4.00	1.00 - 7.00	1.00 - 4.67	1.00 - 6.00
Sum	9.3	54.1	17.7	16.0
Angioedema management*				
Did nothing	2 (50.0%)	4 (44.4%)	3 (50.0%)	2 (40.0%)
Took some prescription or non-prescription medication	3 (75.0%)	6 (66.7%)	3 (50.0%)	4 (80.0%)
Called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	(0.0%)	1 (20.0%)
Went to see doctor, nurse or nurse practitioner	1 (25.0%)	(0.0%)	(0.0%)	(0.0%)
Week 40				
n	38	43	46	46
Number of patients who had angioedema^	6 (15.8%)	10 (23.3%)	7 (15.2%)	4 (8.7%)
Number of days a patient had angioedema per patient				
Mean (SD)	0.31 (0.94)	1.17 (2.48)	0.30 (0.88)	0.15 (0.53)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 5.3	0.0 - 7.0	0.0 - 5.0	0.0 - 2.3
Sum	12	51	14	7
Number of days a patient had angioedema per patient (patients with angioedema)				
Mean (SD)	1.9 (1.7)	5.0 (2.6)	2.0 (1.4)	1.8 (0.7)
Median	1.2	7.0	1.4	1.9
Range	1.00 - 5.25	1.00 - 7.00	1.00 - 5.00	1.00 - 2.33
Sum	11.7	50.5	13.8	7.1
Angioedema management*				
Did nothing	1 (16.7%)	4 (40.0%)	5 (71.4%)	(0.0%)
Took some prescription or non-prescription medication	5 (83.3%)	7 (70.0%)	3 (42.9%)	4 (100.0%)
Called doctor, nurse or nurse practitioner	1 (16.7%)	(0.0%)	(0.0%)	(0.0%)
Was hospitalized	1 (16.7%)	(0.0%)	(0.0%)	(0.0%)

^Percents of patients who had angioedema is based on n (the number of patients who had non-missing data).
Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.
*Percents for types of angioedema management are based on all patients who experienced angioedema in the treatment group.

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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Baseline				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	2 (2.6%)	6 (7.5%)	4 (4.9%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.01 (0.11)	0.04 (0.25)	0.19 (0.89)	0.09 (0.42)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.0	0.0 - 2.0	0.0 - 7.0	0.0 - 3.0
Week 1				
Number of patients who called doctor, nurse or nurse practitioner	5 (6.3%)	3 (3.9%)	3 (3.8%)	5 (6.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.11 (0.49)	0.05 (0.23)	0.11 (0.80)	0.11 (0.43)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.5	0.0 - 1.4	0.0 - 7.0	0.0 - 2.3
Week 2				
Number of patients who called doctor, nurse or nurse practitioner	2 (2.5%)	3 (3.9%)	1 (1.3%)	(0.0%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.04 (0.25)	0.05 (0.28)	0.09 (0.78)	0.00 (0.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 2.0	0.0 - 2.0	0.0 - 7.0	0.0 - 0.0
Week 3				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	3 (3.9%)	6 (7.5%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.28)	0.19 (0.89)	0.01 (0.11)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.0	0.0 - 7.0	0.0 - 1.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 4				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	(0.0%)	3 (3.8%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.01 (0.12)	0.00 (0.00)	0.12 (0.82)	0.01 (0.11)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.0	0.0 - 0.0	0.0 - 7.0	0.0 - 1.0
Week 5				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	1 (1.3%)	3 (3.8%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.02 (0.15)	0.14 (0.87)	0.05 (0.24)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 7.0	0.0 - 1.4
Week 6				
Number of patients who called doctor, nurse or nurse practitioner	2 (2.5%)	1 (1.3%)	3 (3.8%)	(0.0%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.04 (0.24)	0.01 (0.12)	0.13 (0.83)	0.00 (0.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.8	0.0 - 1.0	0.0 - 7.0	0.0 - 0.0
Week 7				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	(0.0%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.26)	0.01 (0.12)	0.00 (0.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.0	0.0 - 1.0	0.0 - 0.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 8				
Number of patients who called doctor, nurse or nurse practitioner	2 (2.5%)	2 (2.6%)	3 (3.8%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.04 (0.24)	0.03 (0.17)	0.06 (0.31)	0.02 (0.17)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.8	0.0 - 1.0	0.0 - 2.0	0.0 - 1.4
Week 9				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.21)	0.00 (0.00)	0.06 (0.30)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 1.8
Week 10				
Number of patients who called doctor, nurse or nurse practitioner	2 (2.5%)	3 (3.9%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.03 (0.18)	0.05 (0.24)	0.00 (0.00)	0.03 (0.16)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.0	0.0 - 1.4	0.0 - 0.0	0.0 - 1.0
Week 11				
Number of patients who called doctor, nurse or nurse practitioner	3 (3.8%)	1 (1.3%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.07 (0.34)	0.02 (0.12)	0.00 (0.00)	0.03 (0.17)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 2.3	0.0 - 1.0	0.0 - 0.0	0.0 - 1.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 12				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.04 (0.29)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 2.3	0.0 - 0.0	0.0 - 0.0	0.0 - 0.0
Week 13				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	(0.0%)	1 (1.3%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.00 (0.00)	0.02 (0.13)	0.08 (0.40)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 0.0	0.0 - 1.0	0.0 - 2.8
Week 14				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.02 (0.14)	0.00 (0.00)	0.06 (0.48)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 4.0
Week 15				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.02 (0.15)	0.00 (0.00)	0.00 (0.00)	0.04 (0.36)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.2	0.0 - 0.0	0.0 - 0.0	0.0 - 3.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 16				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	4 (5.2%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.06 (0.24)	0.00 (0.00)	0.07 (0.49)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.0	0.0 - 0.0	0.0 - 4.0
Week 17				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.22)	0.03 (0.23)	0.02 (0.18)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 1.8	0.0 - 1.4
Week 18				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.03 (0.19)	0.00 (0.00)	0.00 (0.00)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 0.0
Week 19				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	2 (2.6%)	(0.0%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.05 (0.40)	0.06 (0.31)	0.00 (0.00)	0.03 (0.24)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 3.0	0.0 - 2.0	0.0 - 0.0	0.0 - 2.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 20				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	1 (1.3%)	(0.0%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.02 (0.13)	0.00 (0.00)	0.03 (0.29)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.0	0.0 - 0.0	0.0 - 2.3
Week 21				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.27)	0.03 (0.19)	0.11 (0.86)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.8	0.0 - 1.4	0.0 - 7.0
Week 22				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	3 (3.9%)	1 (1.3%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.06 (0.28)	0.02 (0.15)	0.08 (0.70)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.8	0.0 - 1.2	0.0 - 5.8
Week 23				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	1 (1.3%)	1 (1.3%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.02 (0.13)	0.02 (0.18)	0.02 (0.14)	0.10 (0.86)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.0	0.0 - 1.4	0.0 - 1.0	0.0 - 7.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 24				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.32)	0.00 (0.00)	0.07 (0.50)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.3	0.0 - 0.0	0.0 - 4.0
Week 25				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	4 (5.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.08 (0.47)	0.11 (0.47)	0.11 (0.66)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 3.5	0.0 - 3.0	0.0 - 5.3
Week 26				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	1 (1.3%)	2 (2.5%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.02 (0.17)	0.03 (0.26)	0.04 (0.21)	0.13 (0.70)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.2	0.0 - 2.0	0.0 - 1.2	0.0 - 5.0
Week 27				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	4 (5.2%)	(0.0%)	4 (4.9%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.12 (0.56)	0.00 (0.00)	0.11 (0.60)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 4.0	0.0 - 0.0	0.0 - 4.7

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 28				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	3 (3.9%)	2 (2.5%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.08 (0.36)	0.04 (0.20)	0.11 (0.59)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.3	0.0 - 1.0	0.0 - 4.2
Week 29				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	5 (6.5%)	(0.0%)	1 (1.2%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.10 (0.32)	0.00 (0.00)	0.03 (0.25)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 2.0
Week 30				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.21)	0.02 (0.17)	0.04 (0.22)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 1.2	0.0 - 1.4
Week 31				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	1 (1.3%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.33)	0.00 (0.00)	0.13 (0.80)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.3	0.0 - 0.0	0.0 - 5.8

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 32				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	4 (4.9%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.20)	0.02 (0.14)	0.14 (0.63)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.0	0.0 - 1.0	0.0 - 4.2
Week 33				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	3 (3.9%)	(0.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.11 (0.45)	0.00 (0.00)	0.18 (0.83)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.0	0.0 - 0.0	0.0 - 4.7
Week 34				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.22)	0.00 (0.00)	0.12 (0.60)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 3.5
Week 35				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	4 (5.2%)	(0.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.13 (0.43)	0.00 (0.00)	0.18 (0.83)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 2.0	0.0 - 0.0	0.0 - 5.0

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 36				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	3 (3.9%)	(0.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.11 (0.48)	0.00 (0.00)	0.15 (0.70)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 3.0	0.0 - 0.0	0.0 - 4.2
Week 37				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.04 (0.22)	0.00 (0.00)	0.17 (0.85)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 5.0
Week 38				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	1 (1.3%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.25)	0.02 (0.14)	0.13 (0.60)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.4	0.0 - 1.0	0.0 - 4.0
Week 39				
Number of patients who called doctor, nurse or nurse practitioner	(0.0%)	2 (2.6%)	(0.0%)	3 (3.7%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.00 (0.00)	0.05 (0.23)	0.00 (0.00)	0.09 (0.39)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 0.0	0.0 - 1.2	0.0 - 0.0	0.0 - 2.3

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/33
Call Healthcare Provider for CIU
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 40				
Number of patients who called doctor, nurse or nurse practitioner	1 (1.3%)	1 (1.3%)	1 (1.3%)	2 (2.5%)
Number of days a patient called doctor, nurse or nurse practitioner				
Mean (SD)	0.05 (0.28)	0.03 (0.18)	0.03 (0.17)	0.10 (0.54)
Median	0.0	0.0	0.0	0.0
Range	0.0 - 1.8	0.0 - 1.2	0.0 - 1.2	0.0 - 3.5

Baseline weekly numbers are calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hcu)
Database (CLOSED) Datasets (pat diaryeff)
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Table 14.2/32.2
Correlation between Change from Baseline in Basophil High-Affinity Receptor Density (MESF) and Change from Baseline in Weekly Itch Score at Week 12, Week 24 and Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Baseline Basophil High-Affinity Receptor Density (MESF)				
Mean (SD)	219.7 (147.6)	209.3 (140.4)	210.8 (147.2)	204.8 (131.9)
Median	196.5	189.5	200.6	204.1
Range	0.0 - 650.8	0.5 - 563.5	0.0 - 598.5	0.0 - 561.3
Week 12 Basophil High-Affinity Receptor Density (MESF)				
Mean (SD)	253.9 (159.5)	130.3 (127.2)	83.9 (76.7)	43.9 (29.2)
Median	235.5	85.1	61.5	38.1
Range	0.0 - 582.4	0.0 - 517.4	0.7 - 430.1	1.7 - 149.8
% Change from Baseline in Basophil High-Affinity Receptor Density at Week 12				
Mean (SD)	89.2 (362.1)	-5.3 (221.7)	-49.6 (66.1)	141.5 (1575.9)
Median	17.3	-51.1	-70.0	-81.4
Range	-59.5 - 2310.7	-100.0 - 1578.6	-89.1 - 353.2	-99.1 - 11823.3
Change from Baseline in Weekly Itch Score at Week 12				
Mean (SD)	-4.5 (5.7)	-7.7 (6.0)	-8.2 (6.1)	-10.2 (4.9)
Median	-4.0	-7.5	-8.5	-10.5
Range	-18.5 - 7.5	-21.0 - 4.0	-21.0 - 5.0	-19.0 - 0.0
Spearman's Correlation Coefficient between % Change in Basophil High-Affinity Receptor Density and Change in Weekly Itch Score from Baseline at Week 12	0.0584	0.0498	0.1899	0.1982

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_baso_itch2)
Database (CLOSED) Datasets (pat baso diaryeff)
: Generated 28JAN13 10:23 Page 1 of 3

Table 14.2/32.2
Correlation between Change from Baseline in Basophil High-Affinity Receptor Density (MESF) and Change from Baseline in Weekly Itch Score at Week 12, Week 24 and Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Week 24 Basophil High-Affinity Receptor Density (MESF)				
Mean (SD)	294.0 (148.9)	140.3 (128.6)	89.8 (86.8)	50.9 (35.2)
Median	319.1	87.2	62.0	40.3
Range	1.3 - 536.3	1.8 - 550.4	1.7 - 401.4	0.8 - 181.2
% Change from Baseline in Basophil High-Affinity Receptor Density at Week 24				
Mean (SD)	54.0 (77.8)	182.6 (1414.5)	-41.4 (98.3)	230.6 (1998.5)
Median	36.4	-42.2	-64.5	-81.1
Range	-97.7 - 292.5	-94.6 - 10369.8	-92.2 - 531.8	-98.1 - 14324.8
Change from Baseline in Weekly Itch Score at Week 24				
Mean (SD)	-8.3 (5.1)	-8.6 (6.1)	-9.9 (4.9)	-11.1 (4.6)
Median	-8.0	-9.5	-10.0	-11.5
Range	-21.0 - 4.0	-21.0 - 4.5	-18.5 - 0.0	-19.0 - -0.5
Spearman's Correlation Coefficient between % Change in Basophil High-Affinity Receptor Density and Change in Weekly Itch Score from Baseline at Week 24	-.0345	0.0450	0.3461	-.0754
Week 40 Basophil High-Affinity Receptor Density (MESF)				
Mean (SD)	282.3 (165.9)	281.4 (159.9)	254.4 (144.3)	256.7 (151.6)
Median	343.6	296.8	270.6	247.3
Range	0.0 - 567.7	42.1 - 599.0	0.6 - 563.3	15.1 - 640.0

Table 14.2/32.2
Correlation between Change from Baseline in Basophil High-Affinity Receptor Density (MESF) and Change from Baseline in Weekly Itch Score at Week 12, Week 24 and Week 40
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
% Change from Baseline in Basophil High-Affinity Receptor Density at Week 40				
Mean (SD)	57.0 (92.2)	79.0 (260.0)	76.6 (215.1)	1104.8 (7185.1)
Median	29.2	25.9	29.4	19.8
Range	-100.0 - 283.1	-52.8 - 1843.3	-99.8 - 1045.3	-79.4 - 50858.7
Change from Baseline in Weekly Itch Score at Week 40				
Mean (SD)	-7.3 (6.0)	-6.9 (6.4)	-6.3 (6.3)	-5.6 (7.0)
Median	-8.6	-7.5	-8.0	-6.0
Range	-16.5 - 4.0	-21.0 - 3.0	-16.5 - 11.5	-19.0 - 9.9
Spearman's Correlation Coefficient between % Change in Basophil High-Affinity Receptor Density and Change in Weekly Itch Score from Baseline at Week 40	-.2104	-.2647	-.2980	-.1288

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_baso_itch2)
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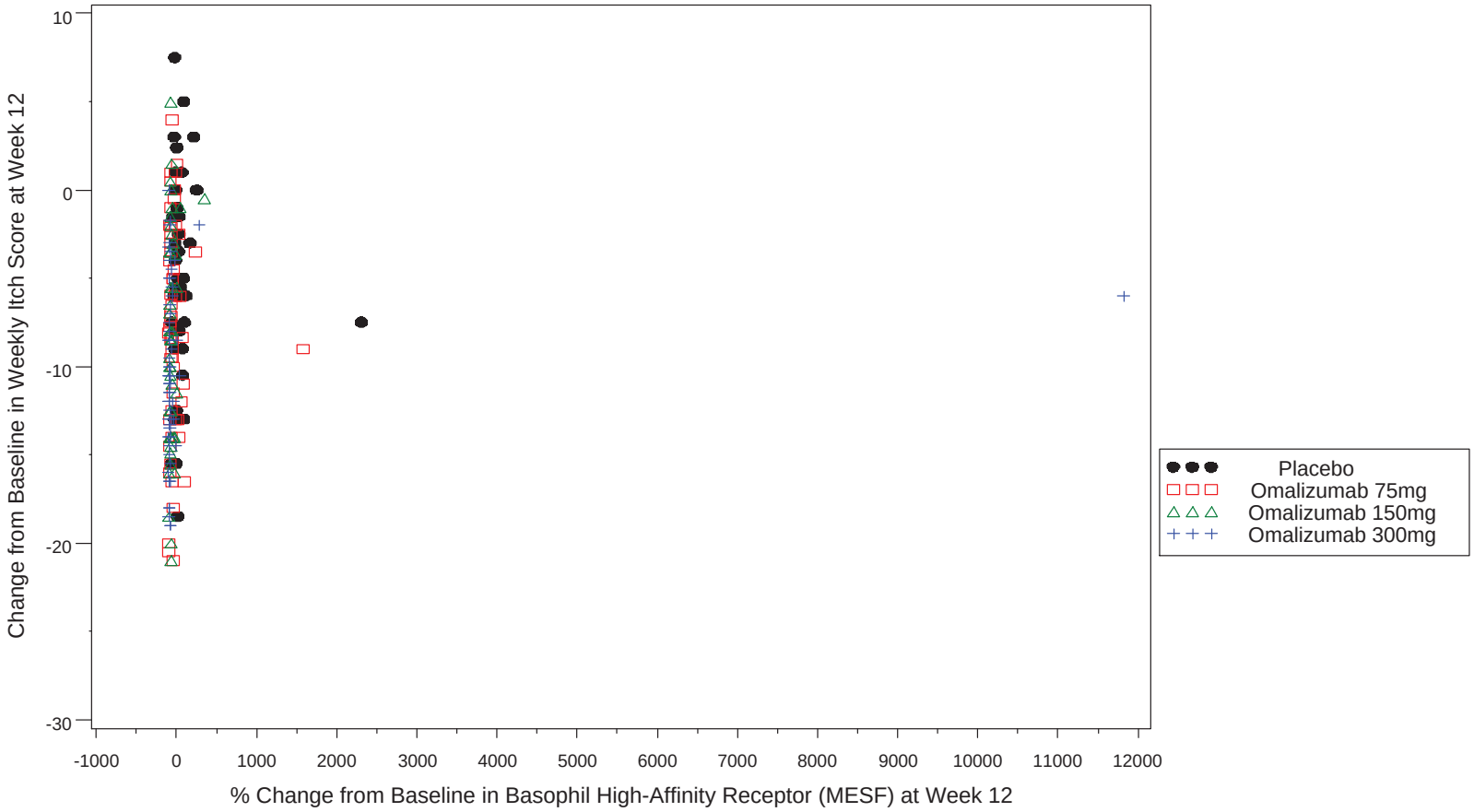
: Generated 28JAN13 10:23 Page 3 of 3

Figure 14.2/8.1
Scatterplot of % Change from Baseline in Basophil High-Affinity Receptor Density (MESF) by Change from Baseline in Weekly Itch Score at Week 12
Modified Intention to Treat Patients



Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_baso_scatter)
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: Generated 24JAN13 07:24 Page 1 of 1

Figure 14.2/8.2
Scatterplot of % Change from Baseline in Basophil High-Affinity Receptor Density (MESF) byChange from Baseline in Weekly Itch Score at Week 24
Modified Intention to Treat Patients

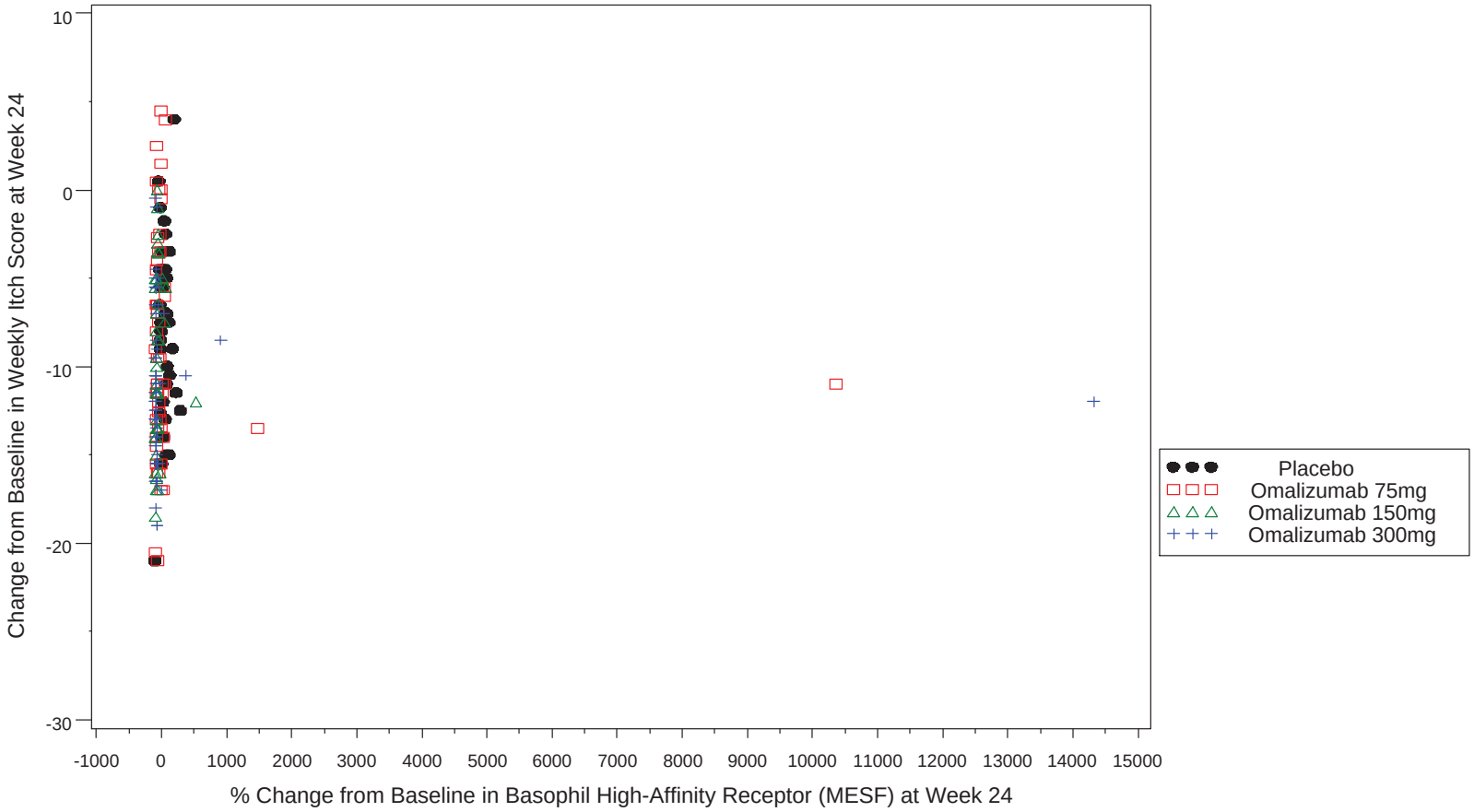

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Figure 14.2/8.3
Scatterplot of % Change from Baseline in Basophil High-Affinity Receptor Density (MESF) by Change from Baseline in Weekly Itch Score at Week 40
Modified Intention to Treat Patients

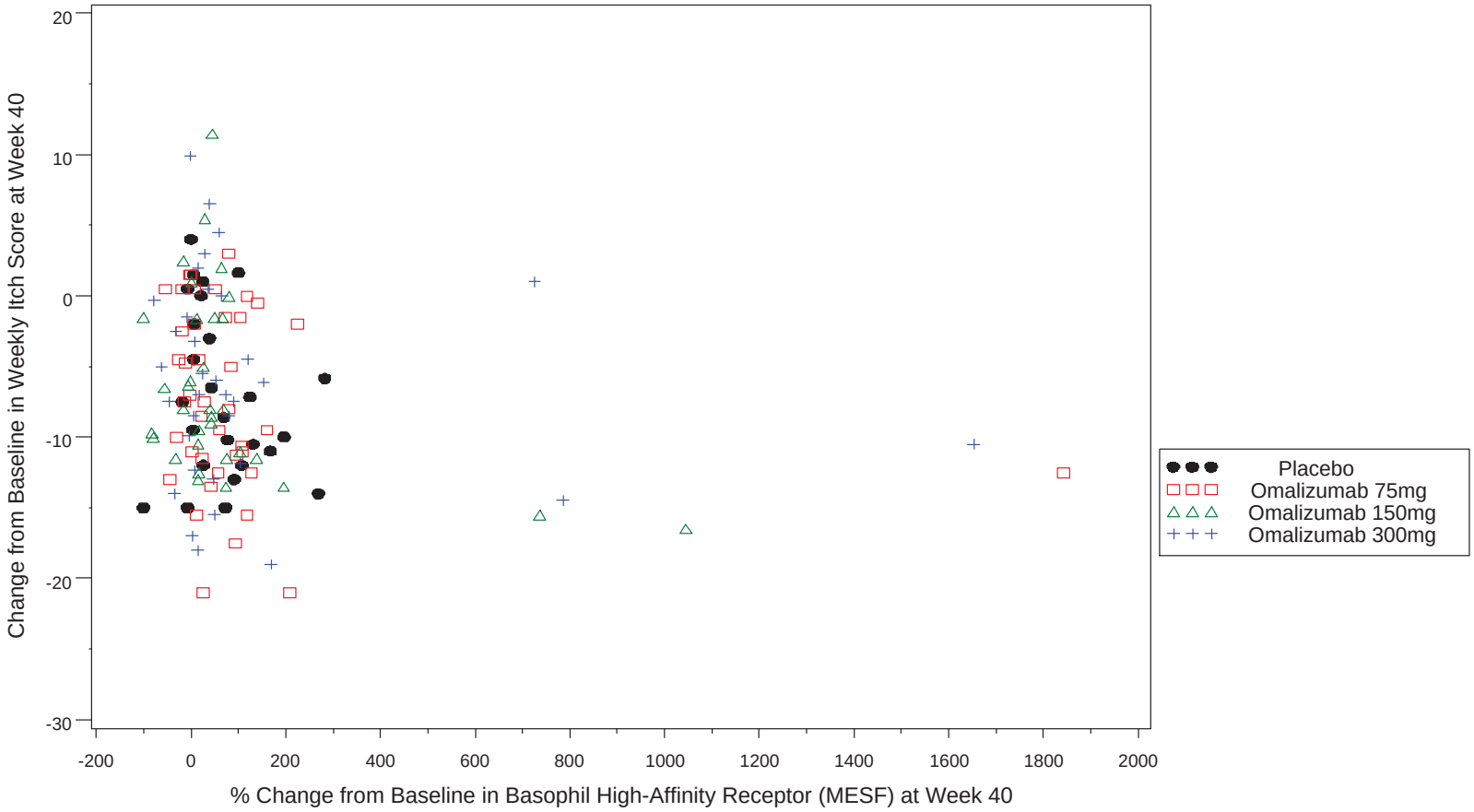

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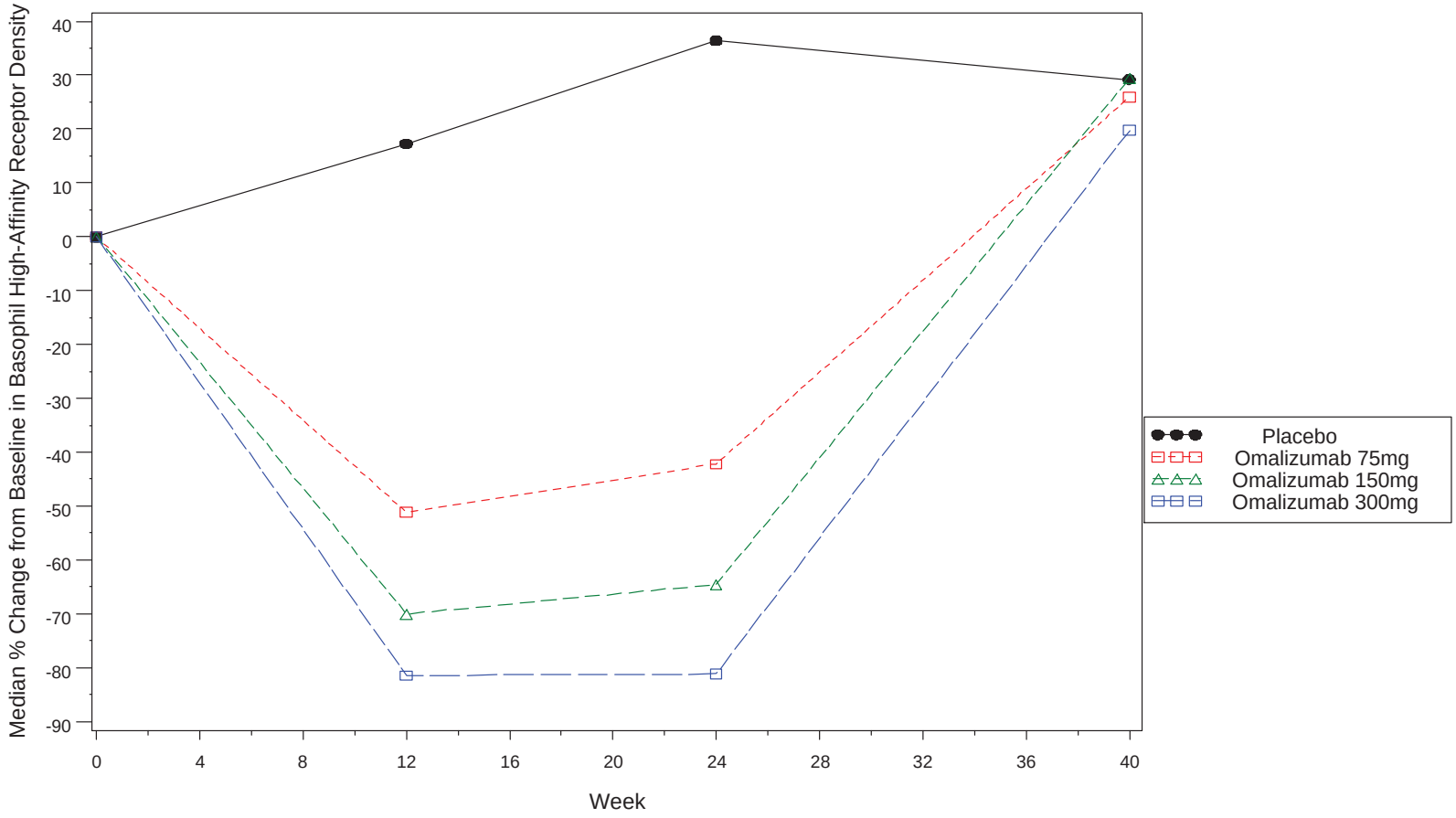
Figure 14.2/10
Median % Change from Baseline in Basophil High-Affinity Receptor Density (MESF) by Study Visit
Modified Intention to Treat Patients



Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_baso)
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: Generated 28FEB13 09:52 Page 1 of 1

Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
First Half of Treatment Period (Day1-Week12)	Proportion of days with morning entry				
	n	80	77	80	81
	Mean (SD)	93.7% (10.0%)	92.7% (15.5%)	94.9% (9.2%)	95.1% (7.4%)
	Median	97.0%	97.6%	97.6%	97.6%
	Range	26.2% - 100.0%	4.8% - 100.0%	34.5% - 100.0%	69.0% - 100.0%
	Proportion of days with evening entry				
	n	80	77	80	81
	Mean (SD)	93.5% (10.2%)	91.8% (15.9%)	94.8% (8.4%)	94.6% (9.0%)
	Median	96.4%	97.6%	97.6%	97.6%
	Range	25.0% - 100.0%	2.4% - 100.0%	36.9% - 100.0%	47.6% - 100.0%
	Proportion of days with both morning and evening daily entry				
	n	80	77	80	81
	Mean (SD)	89.4% (11.9%)	88.0% (17.8%)	90.9% (12.6%)	90.8% (11.8%)
	Median	91.7%	95.2%	95.0%	96.4%
	Range	20.2% - 100.0%	2.4% - 100.0%	13.1% - 100.0%	39.3% - 100.0%
	Proportion of days with at least one (morning or evening) daily entry				
	n	80	77	80	81
	Mean (SD)	97.8% (8.8%)	96.5% (14.5%)	98.8% (5.0%)	98.9% (3.7%)
	Median	100.0%	100.0%	100.0%	100.0%
	Range	31.0% - 100.0%	4.8% - 100.0%	58.3% - 100.0%	78.6% - 100.0%

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
First Half of Treatment Period (Day1-Week12)	Proportion of days with at least one (morning or evening) daily entry				
	>85 %	77 (96.3%)	74 (96.1%)	79 (98.8%)	79 (97.5%)
	50-85 %	2 (2.5%)	1 (1.3%)	1 (1.3%)	2 (2.5%)
	<50 %	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)
Second Half of Treatment Period (Week12-Week24)	Proportion of days with morning entry				
	n	63	68	64	72
	Mean (SD)	90.6% (12.9%)	90.6% (16.0%)	92.1% (10.8%)	92.6% (13.1%)
	Median	96.6%	96.4%	96.4%	97.6%
	Range	42.9% - 100.0%	18.1% - 100.0%	45.2% - 100.0%	34.6% - 100.0%
	Proportion of days with evening entry				
	n	63	68	64	72
	Mean (SD)	91.0% (10.9%)	90.1% (15.6%)	91.5% (10.4%)	91.9% (13.1%)
	Median	94.0%	95.8%	95.9%	96.5%
	Range	36.4% - 100.0%	15.7% - 100.0%	58.3% - 100.0%	29.9% - 100.0%
	Proportion of days with both morning and evening daily entry				
	n	63	68	64	72
	Mean (SD)	84.1% (16.5%)	84.6% (19.8%)	86.1% (15.3%)	87.0% (18.5%)
	Median	89.4%	92.9%	91.1%	93.7%
	Range	21.6% - 100.0%	10.8% - 100.0%	28.6% - 100.0%	11.1% - 100.0%

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
Database (CLOSED) Datasets (pat pateff)
: Generated 25JAN13 14:04 Page 2 of 7

Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Second Half of Treatment Period (Week12-Week24)	Proportion of days with at least one (morning or evening) daily entry				
	n	63	68	64	72
	Mean (SD)	97.5% (6.4%)	96.1% (12.5%)	97.5% (5.6%)	97.5% (7.8%)
	Median	100.0%	100.0%	100.0%	100.0%
	Range	63.6% - 100.0%	22.9% - 100.0%	73.5% - 100.0%	59.8% - 100.0%
	Proportion of days with at least one (morning or evening) daily entry				
	>85 %	60 (75.0%)	65 (84.4%)	60 (75.0%)	68 (84.0%)
	50-85 %	3 (3.8%)	1 (1.3%)	4 (5.0%)	4 (4.9%)
	<50 %	(0.0%)	2 (2.6%)	(0.0%)	(0.0%)
	Missing	17 (21.3%)	9 (11.7%)	16 (20.0%)	9 (11.1%)
Treatment Period (Day1 - Week24)	Proportion of days with morning entry				
	n	80	77	80	81
	Mean (SD)	92.7% (9.7%)	91.2% (15.9%)	94.1% (9.0%)	94.1% (9.4%)
	Median	96.4%	97.6%	97.4%	97.6%
	Range	37.8% - 100.0%	11.4% - 100.0%	50.3% - 100.0%	56.4% - 100.0%
	Proportion of days with evening entry				
	n	80	77	80	81
	Mean (SD)	92.4% (10.0%)	90.6% (15.8%)	93.6% (8.4%)	93.2% (10.1%)
	Median	94.6%	95.8%	96.5%	97.0%
	Range	30.8% - 100.0%	9.0% - 100.0%	51.5% - 100.0%	39.0% - 100.0%

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Treatment Period (Day1 - Week24)	Proportion of days with both morning and evening daily entry				
	n	80	77	80	81
	Mean (SD)	87.5% (12.4%)	86.0% (18.5%)	89.3% (12.6%)	89.1% (14.1%)
	Median	90.4%	93.9%	92.4%	95.2%
	Range	20.9% - 100.0%	6.6% - 100.0%	35.9% - 100.0%	25.6% - 100.0%
	Proportion of days with at least one (morning or evening) daily entry				
	n	80	77	80	81
	Mean (SD)	97.6% (7.5%)	95.8% (14.2%)	98.4% (4.7%)	98.2% (5.0%)
	Median	100.0%	100.0%	100.0%	100.0%
	Range	47.7% - 100.0%	13.8% - 100.0%	65.9% - 100.0%	69.8% - 100.0%
	Proportion of days with at least one (morning or evening) daily entry				
	>85 %	76 (95.0%)	72 (93.5%)	78 (97.5%)	78 (96.3%)
	50-85 %	3 (3.8%)	3 (3.9%)	2 (2.5%)	3 (3.7%)
	<50 %	1 (1.3%)	2 (2.6%)	(0.0%)	(0.0%)
Follow-up Period (Week24 - Week40)	Proportion of days with morning entry				
	n	77	73	80	78
	Mean (SD)	85.7% (19.7%)	85.7% (16.4%)	87.3% (15.1%)	88.8% (17.5%)
	Median	92.0%	92.0%	92.9%	95.5%
	Range	0.8% - 100.0%	27.3% - 100.0%	33.3% - 100.0%	10.9% - 100.0%

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
Database (CLOSED) Datasets (pat pateff)
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Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Follow-up Period (Week24 - Week40)	Proportion of days with evening entry				
	n	71	73	80	77
	Mean (SD)	84.3% (17.2%)	85.6% (15.9%)	85.2% (16.0%)	88.7% (14.2%)
	Median	89.1%	91.2%	91.4%	93.3%
	Range	2.6% - 99.2%	18.2% - 99.1%	8.3% - 99.1%	8.7% - 100.0%
	Proportion of days with both morning and evening daily entry				
	n	71	73	80	77
	Mean (SD)	77.6% (20.6%)	78.2% (20.0%)	78.2% (20.5%)	83.5% (17.9%)
	Median	83.3%	85.0%	85.8%	89.1%
	Range	2.6% - 99.1%	9.1% - 99.1%	8.3% - 99.1%	5.1% - 99.1%
	Proportion of days with at least one (morning or evening) daily entry				
	n	77	73	80	78
	Mean (SD)	91.9% (18.2%)	93.1% (12.7%)	94.3% (10.2%)	94.0% (15.2%)
	Median	97.7%	98.2%	98.2%	99.1%
	Range	0.8% - 100.0%	36.4% - 100.0%	33.3% - 100.0%	11.1% - 100.0%
	Proportion of days with at least one (morning or evening) daily entry				
	>85 %	70 (87.5%)	62 (80.5%)	69 (86.3%)	69 (85.2%)
	50-85 %	5 (6.3%)	9 (11.7%)	10 (12.5%)	7 (8.6%)
	<50 %	2 (2.5%)	2 (2.6%)	1 (1.3%)	2 (2.5%)
	Missing	3 (3.8%)	4 (5.2%)	(0.0%)	3 (3.7%)

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
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Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Study (Day1 - Week40)	Proportion of days with morning entry				
	n	80	77	80	81
	Mean (SD)	88.7% (13.1%)	87.8% (16.6%)	91.2% (9.7%)	91.1% (12.4%)
	Median	93.4%	95.4%	94.7%	95.9%
	Range	40.6% - 100.0%	7.0% - 100.0%	53.7% - 100.0%	36.1% - 100.0%
	Proportion of days with evening entry				
	n	80	77	80	81
	Mean (SD)	87.8% (13.4%)	87.4% (16.0%)	90.3% (9.5%)	90.2% (13.5%)
	Median	91.3%	93.6%	94.0%	95.0%
	Range	32.9% - 99.6%	7.0% - 99.6%	59.1% - 99.6%	25.5% - 99.6%
	Proportion of days with both morning and evening daily entry				
	n	80	77	80	81
	Mean (SD)	82.3% (15.6%)	81.8% (18.9%)	84.8% (13.8%)	85.7% (16.4%)
	Median	86.9%	89.0%	89.9%	92.1%
	Range	22.6% - 99.6%	5.1% - 99.6%	39.5% - 99.6%	16.5% - 99.6%
	Proportion of days with at least one (morning or evening) daily entry				
	n	80	77	80	81
	Mean (SD)	94.2% (11.8%)	93.4% (14.5%)	96.7% (5.1%)	95.6% (9.8%)
	Median	98.6%	98.9%	98.9%	99.3%
	Range	44.0% - 100.0%	8.9% - 100.0%	77.2% - 100.0%	45.2% - 100.0%

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
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Table 14.2/1
Daily Diary Compliance Rate
Modified Intention to Treat Patients

		Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Study (Day1 - Week40)	Proportion of days with at least one (morning or evening) daily entry				
	>85 %	71 (88.8%)	68 (88.3%)	76 (95.0%)	74 (91.4%)
	50-85 %	8 (10.0%)	7 (9.1%)	4 (5.0%)	6 (7.4%)
	<50 %	1 (1.3%)	2 (2.6%)	(0.0%)	1 (1.2%)

*Compliance rate is defined as number of daily non-missing diary entry/ total number of days during a period.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_diary_comp)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Baseline																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	14.37	3.48	14.0	8.0	21.0						
Omalizumab 75mg	77	14.47	3.60	14.0	8.5	21.0	14.47	3.60	14.0	8.5	21.0						
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	14.09	3.77	14.0	8.0	21.0						
Omalizumab 300mg	81	14.20	3.31	14.0	8.0	21.0	14.20	3.31	14.0	8.0	21.0						
Week 1																	
Placebo	80	14.37	3.48	14.0	8.0	21.0	12.34	3.96	12.5	4.0	21.0	-2.02	3.22	0.36	-2.0	-11.5	6.0
Omalizumab 75mg	76	14.55	3.56	14.0	8.5	21.0	11.44	4.31	11.5	3.5	21.0	-3.11	4.08	0.47	-3.0	-12.0	5.5
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	10.85	4.91	10.3	0.5	21.0	-3.24	4.22	0.47	-2.7	-14.0	4.5
Omalizumab 300mg	80	14.19	3.33	14.0	8.0	21.0	8.78	4.29	9.0	1.0	18.0	-5.40	4.42	0.49	-5.0	-17.0	5.5
Week 2																	
Placebo	77	14.29	3.43	14.0	8.0	21.0	11.02	5.07	12.0	0.0	19.0	-3.27	4.75	0.54	-2.5	-15.5	5.1
Omalizumab 75mg	75	14.47	3.52	14.0	8.5	21.0	9.68	5.85	9.5	0.0	21.0	-4.79	5.76	0.66	-4.5	-19.0	5.8
Omalizumab 150mg	80	14.09	3.77	14.0	8.0	21.0	9.05	5.77	8.0	0.0	21.0	-5.04	5.57	0.62	-5.0	-18.5	5.5
Omalizumab 300mg	78	14.04	3.24	14.0	8.0	21.0	6.04	5.02	6.0	0.0	18.5	-8.00	5.46	0.62	-7.0	-21.0	1.0
Week 3																	
Placebo	77	14.29	3.43	14.0	8.0	21.0	10.35	4.78	11.0	0.0	20.5	-3.94	4.63	0.53	-3.0	-15.5	8.0
Omalizumab 75mg	73	14.41	3.51	14.0	8.5	21.0	9.66	5.20	9.5	0.0	21.0	-4.75	4.91	0.57	-4.0	-17.5	7.0
Omalizumab 150mg	79	14.08	3.80	14.0	8.0	21.0	8.63	5.94	8.0	0.0	21.0	-5.44	5.68	0.64	-5.0	-18.0	6.5
Omalizumab 300mg	78	14.04	3.24	14.0	8.0	21.0	5.67	5.40	4.5	0.0	18.0	-8.37	5.85	0.66	-8.0	-21.0	3.5
Week 4																	
Placebo	73	14.18	3.41	14.0	8.0	21.0	10.68	5.06	11.1	0.0	21.0	-3.50	4.57	0.54	-2.5	-15.5	5.5
Omalizumab 75mg	71	14.40	3.53	14.0	8.5	21.0	10.13	5.47	9.5	0.0	21.0	-4.27	5.16	0.61	-2.9	-15.5	6.5
Omalizumab 150mg	76	14.11	3.79	14.0	8.0	21.0	9.15	5.99	8.9	0.0	21.0	-4.96	5.47	0.63	-4.7	-21.0	5.5
Omalizumab 300mg	76	14.07	3.27	14.0	8.0	21.0	5.79	5.51	5.6	0.0	18.5	-8.28	5.72	0.66	-7.8	-19.0	5.5
Week 5																	
Placebo	69	14.23	3.46	14.0	8.0	21.0	9.18	5.05	9.5	0.0	17.5	-5.06	5.16	0.62	-4.5	-17.5	5.1
Omalizumab 75mg	65	14.56	3.57	14.0	8.5	21.0	7.88	5.71	7.9	0.0	21.0	-6.68	5.84	0.72	-5.5	-20.5	5.0
Omalizumab 150mg	69	13.76	3.67	14.0	8.0	21.0	7.72	5.73	8.0	0.0	21.0	-6.04	6.08	0.73	-5.6	-21.0	6.1
Omalizumab 300mg	74	14.07	3.30	14.0	8.0	21.0	5.02	5.33	4.3	0.0	19.0	-9.05	5.60	0.65	-9.3	-19.0	4.5

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 6																	
Placebo	70	14.04	3.42	14.0	8.0	21.0	8.97	5.35	9.0	0.0	17.5	-5.06	5.43	0.65	-3.6	-19.0	4.0
Omalizumab 75mg	72	14.42	3.54	14.0	8.5	21.0	7.21	5.59	6.2	0.0	21.0	-7.21	5.97	0.70	-7.5	-20.5	5.5
Omalizumab 150mg	75	14.03	3.75	14.0	8.0	21.0	7.49	6.07	6.5	0.0	21.0	-6.54	6.14	0.71	-5.9	-21.0	6.5
Omalizumab 300mg	75	14.03	3.30	14.0	8.0	21.0	4.40	4.87	2.3	0.0	15.5	-9.63	5.16	0.60	-9.5	-21.0	2.5
Week 7																	
Placebo	69	13.97	3.40	14.0	8.0	21.0	9.21	4.98	9.5	0.0	18.5	-4.76	5.20	0.63	-4.5	-17.5	5.0
Omalizumab 75mg	72	14.42	3.54	14.0	8.5	21.0	7.95	6.28	7.0	0.0	21.0	-6.47	5.97	0.70	-7.0	-20.5	5.0
Omalizumab 150mg	73	13.95	3.73	14.0	8.0	21.0	6.40	5.89	6.0	0.0	21.0	-7.55	6.18	0.72	-8.0	-21.0	6.0
Omalizumab 300mg	76	14.03	3.28	14.0	8.0	21.0	4.42	4.97	2.3	0.0	15.5	-9.61	5.62	0.64	-9.3	-21.0	2.5
Week 8																	
Placebo	67	13.85	3.36	14.0	8.0	21.0	9.26	4.95	9.5	0.0	19.5	-4.59	5.25	0.64	-3.5	-19.0	5.0
Omalizumab 75mg	68	14.51	3.54	14.0	8.5	21.0	8.63	6.57	7.8	0.0	21.0	-5.88	6.10	0.74	-5.9	-21.0	6.0
Omalizumab 150mg	69	13.95	3.70	14.0	8.0	21.0	6.19	6.05	4.5	0.0	21.0	-7.76	6.40	0.77	-7.6	-21.0	11.0
Omalizumab 300mg	73	14.00	3.27	14.0	8.0	21.0	4.63	5.30	2.0	0.0	17.5	-9.37	5.77	0.68	-9.5	-21.0	5.5
Week 9																	
Placebo	60	13.68	3.35	13.8	8.0	21.0	8.68	5.46	9.9	0.0	19.0	-5.00	5.68	0.73	-4.8	-19.0	6.0
Omalizumab 75mg	62	14.80	3.60	14.0	8.5	21.0	7.63	6.05	6.8	0.0	21.0	-7.17	6.02	0.76	-6.6	-21.0	5.0
Omalizumab 150mg	61	14.21	3.59	14.0	8.0	21.0	5.16	5.20	4.0	0.0	16.1	-9.05	5.64	0.72	-9.3	-21.0	2.0
Omalizumab 300mg	68	14.04	3.32	14.0	8.0	21.0	4.09	4.69	2.4	0.0	16.1	-9.95	5.18	0.63	-9.5	-21.0	4.5
Week 10																	
Placebo	64	13.80	3.26	14.0	8.0	21.0	8.81	5.05	9.0	0.0	18.5	-4.99	5.49	0.69	-4.8	-18.0	8.0
Omalizumab 75mg	68	14.61	3.53	14.0	8.5	21.0	6.81	5.80	6.3	0.0	21.0	-7.80	6.23	0.76	-8.3	-21.0	6.0
Omalizumab 150mg	67	13.81	3.57	14.0	8.0	21.0	5.04	4.81	4.0	0.0	19.0	-8.77	5.81	0.71	-9.0	-21.0	5.0
Omalizumab 300mg	74	14.12	3.27	14.0	8.0	21.0	4.08	4.84	2.0	0.0	18.9	-10.04	5.51	0.64	-10.5	-21.0	4.0
Week 11																	
Placebo	64	13.71	3.34	14.0	8.0	21.0	8.89	5.24	8.8	0.0	21.0	-4.82	5.22	0.65	-4.3	-18.5	5.8
Omalizumab 75mg	68	14.61	3.53	14.0	8.5	21.0	7.10	5.61	7.0	0.0	21.0	-7.51	5.94	0.72	-7.5	-21.0	4.0
Omalizumab 150mg	66	13.79	3.59	14.0	8.0	21.0	4.66	4.76	3.0	0.0	15.0	-9.12	5.89	0.72	-9.5	-21.0	4.5
Omalizumab 300mg	74	14.12	3.27	14.0	8.0	21.0	3.80	4.50	2.0	0.0	18.0	-10.32	5.27	0.61	-10.8	-21.0	2.5

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 12																	
Placebo	64	13.71	3.34	14.0	8.0	21.0	9.17	5.53	8.3	0.0	20.5	-4.54	5.48	0.69	-4.0	-18.5	7.5
Omalizumab 75mg	66	14.70	3.52	14.0	8.5	21.0	7.17	5.80	7.0	0.0	21.0	-7.54	5.99	0.74	-7.3	-21.0	4.0
Omalizumab 150mg	64	13.67	3.53	14.0	8.0	21.0	5.35	5.28	3.5	0.0	19.5	-8.32	5.95	0.74	-8.5	-21.0	5.0
Omalizumab 300mg	73	14.08	3.30	14.0	8.0	21.0	3.66	4.42	1.5	0.0	19.3	-10.43	5.06	0.59	-10.5	-19.5	0.0
Week 13																	
Placebo	50	13.46	3.39	13.3	8.0	21.0	7.92	4.90	8.5	0.0	18.5	-5.54	5.81	0.82	-5.0	-19.0	6.6
Omalizumab 75mg	61	14.78	3.58	14.0	8.5	21.0	6.32	5.62	6.5	0.0	21.0	-8.46	5.84	0.75	-8.5	-21.0	2.5
Omalizumab 150mg	57	14.23	3.55	14.0	8.0	21.0	5.05	4.80	4.1	0.0	16.3	-9.18	5.62	0.74	-9.5	-21.0	2.3
Omalizumab 300mg	68	14.15	3.32	13.8	8.0	21.0	3.81	4.82	1.3	0.0	19.6	-10.34	5.63	0.68	-11.0	-20.5	2.3
Week 14																	
Placebo	60	13.73	3.42	14.0	8.0	21.0	7.87	5.25	7.5	0.0	21.0	-5.86	5.76	0.74	-5.0	-19.0	8.0
Omalizumab 75mg	66	14.73	3.51	14.0	8.5	21.0	6.07	6.29	3.8	0.0	21.0	-8.66	6.36	0.78	-9.5	-21.0	6.5
Omalizumab 150mg	63	13.90	3.59	14.0	8.0	21.0	4.71	4.37	3.0	0.0	15.0	-9.19	5.17	0.65	-8.5	-19.0	0.5
Omalizumab 300mg	72	14.01	3.27	13.8	8.0	21.0	3.78	4.96	1.3	0.0	18.5	-10.23	5.67	0.67	-11.0	-19.0	6.5
Week 15																	
Placebo	59	13.74	3.45	14.0	8.0	21.0	7.72	4.98	7.5	0.0	18.5	-6.02	5.49	0.71	-6.0	-18.5	5.0
Omalizumab 75mg	65	14.68	3.51	14.0	8.5	21.0	6.60	6.64	4.0	0.0	21.0	-8.07	6.84	0.85	-9.0	-21.0	7.0
Omalizumab 150mg	63	13.90	3.59	14.0	8.0	21.0	5.09	4.82	4.1	0.0	16.0	-8.80	5.67	0.71	-9.0	-19.5	3.0
Omalizumab 300mg	71	14.05	3.28	14.0	8.0	21.0	4.03	5.37	1.0	0.0	20.1	-10.01	6.04	0.72	-11.0	-19.5	7.5
Week 16																	
Placebo	59	13.74	3.45	14.0	8.0	21.0	7.85	5.30	7.0	0.0	20.5	-5.89	5.85	0.76	-6.0	-19.0	5.0
Omalizumab 75mg	66	14.64	3.49	14.0	8.5	21.0	7.29	6.95	5.3	0.0	21.0	-7.36	7.08	0.87	-7.8	-21.0	10.0
Omalizumab 150mg	61	13.91	3.65	14.0	8.0	21.0	5.13	5.13	4.0	0.0	18.7	-8.78	5.43	0.70	-9.0	-21.0	1.5
Omalizumab 300mg	71	14.04	3.29	14.0	8.0	21.0	3.87	5.11	1.0	0.0	20.1	-10.18	5.58	0.66	-11.0	-19.5	2.0
Week 17																	
Placebo	55	13.69	3.50	14.0	8.0	21.0	6.53	5.00	6.5	0.0	17.5	-7.16	5.67	0.76	-7.0	-18.5	4.8
Omalizumab 75mg	59	14.68	3.43	14.0	8.5	21.0	6.05	6.65	3.5	0.0	21.0	-8.63	6.87	0.89	-10.0	-21.0	11.0
Omalizumab 150mg	57	14.06	3.84	14.0	8.0	21.0	4.64	5.35	2.3	0.0	20.0	-9.42	5.93	0.79	-10.0	-21.0	4.1
Omalizumab 300mg	65	13.89	3.33	13.5	8.0	21.0	3.17	4.40	0.7	0.0	20.0	-10.72	4.98	0.62	-11.0	-19.5	0.0

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 18																	
Placebo	57	13.53	3.37	14.0	8.0	21.0	6.89	4.68	7.0	0.0	18.0	-6.64	5.49	0.73	-7.0	-19.0	6.5
Omalizumab 75mg	64	14.86	3.48	14.3	8.5	21.0	5.71	6.82	2.7	0.0	21.0	-9.15	6.96	0.87	-11.0	-21.0	11.0
Omalizumab 150mg	62	13.96	3.72	14.0	8.0	21.0	4.27	4.53	2.3	0.0	15.5	-9.69	5.46	0.69	-9.5	-21.0	-0.5
Omalizumab 300mg	71	14.05	3.28	14.0	8.0	21.0	3.07	4.21	0.5	0.0	20.5	-10.98	4.98	0.59	-11.5	-19.5	1.5
Week 19																	
Placebo	57	13.60	3.46	14.0	8.0	21.0	7.01	5.29	7.0	0.0	21.0	-6.59	5.73	0.76	-7.0	-16.5	9.5
Omalizumab 75mg	64	14.86	3.48	14.3	8.5	21.0	6.45	6.68	4.8	0.0	21.0	-8.41	6.79	0.85	-9.5	-21.0	9.0
Omalizumab 150mg	62	13.96	3.72	14.0	8.0	21.0	4.23	4.35	3.0	0.0	15.8	-9.73	5.42	0.69	-9.0	-21.0	1.5
Omalizumab 300mg	72	14.01	3.27	13.8	8.0	21.0	2.85	4.16	0.5	0.0	19.6	-11.16	4.75	0.56	-11.5	-19.5	0.0
Week 20																	
Placebo	55	13.65	3.41	14.0	8.0	21.0	6.53	5.20	7.0	0.0	21.0	-7.12	5.64	0.76	-8.0	-18.0	5.0
Omalizumab 75mg	61	14.77	3.53	14.0	8.5	21.0	7.03	6.82	5.8	0.0	21.0	-7.74	6.65	0.85	-8.0	-21.0	8.8
Omalizumab 150mg	61	13.96	3.75	14.0	8.0	21.0	4.31	4.42	3.5	0.0	17.5	-9.65	5.31	0.68	-9.5	-21.0	3.5
Omalizumab 300mg	68	14.08	3.34	14.0	8.0	21.0	2.77	4.35	0.5	0.0	20.5	-11.31	4.64	0.56	-11.5	-19.5	0.0
Week 21																	
Placebo	50	13.55	3.43	14.0	8.0	21.0	5.52	4.68	4.3	0.0	14.0	-8.03	5.55	0.79	-8.6	-18.7	2.5
Omalizumab 75mg	59	14.93	3.51	14.0	8.5	21.0	6.58	6.34	5.5	0.0	21.0	-8.35	6.46	0.84	-9.5	-21.0	8.0
Omalizumab 150mg	52	14.38	3.59	14.0	8.5	21.0	4.91	4.90	4.0	0.0	18.9	-9.47	5.52	0.77	-9.5	-21.0	3.5
Omalizumab 300mg	67	14.16	3.33	14.0	8.0	21.0	2.44	4.10	0.0	0.0	20.3	-11.72	4.77	0.58	-12.0	-19.5	1.5
Week 22																	
Placebo	55	13.52	3.38	14.0	8.0	21.0	5.76	5.03	5.5	0.0	20.5	-7.76	5.70	0.77	-8.5	-16.5	9.0
Omalizumab 75mg	64	14.90	3.53	14.3	8.5	21.0	5.78	6.05	4.8	0.0	21.0	-9.12	6.32	0.79	-10.8	-21.0	9.5
Omalizumab 150mg	58	14.17	3.69	14.0	8.0	21.0	5.15	5.46	4.0	0.0	21.0	-9.02	6.31	0.83	-9.0	-21.0	3.5
Omalizumab 300mg	70	14.03	3.31	13.8	8.0	21.0	2.40	4.29	0.0	0.0	20.3	-11.62	4.75	0.57	-12.0	-19.5	0.0
Week 23																	
Placebo	56	13.60	3.40	14.0	8.0	21.0	6.10	5.12	5.5	0.0	19.5	-7.50	5.73	0.77	-8.3	-17.5	8.0
Omalizumab 75mg	63	14.94	3.53	14.5	8.5	21.0	6.35	6.58	4.5	0.0	21.0	-8.59	6.62	0.83	-9.5	-21.0	8.5
Omalizumab 150mg	58	13.96	3.65	14.0	8.0	21.0	4.72	4.58	4.3	0.0	17.5	-9.23	5.91	0.78	-9.5	-21.0	3.5
Omalizumab 300mg	71	14.00	3.29	13.5	8.0	21.0	2.40	4.40	0.0	0.0	21.0	-11.60	4.79	0.57	-11.5	-19.5	2.1

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 24																	
Placebo	55	13.65	3.40	14.0	8.0	21.0	5.79	4.96	5.5	0.0	19.0	-7.86	5.38	0.73	-7.5	-21.0	4.5
Omalizumab 75mg	63	14.94	3.53	14.5	8.5	21.0	6.42	6.31	6.0	0.0	21.0	-8.53	6.09	0.77	-9.5	-21.0	4.5
Omalizumab 150mg	57	13.95	3.68	14.0	8.0	21.0	4.87	5.06	3.0	0.0	20.5	-9.08	5.96	0.79	-9.5	-21.0	10.5
Omalizumab 300mg	70	13.94	3.27	13.5	8.0	21.0	2.55	4.29	0.0	0.0	19.8	-11.38	4.81	0.58	-11.8	-19.5	-0.5
Week 25																	
Placebo	52	13.70	3.47	14.0	8.0	21.0	6.32	4.74	5.7	0.0	19.5	-7.38	5.61	0.78	-8.3	-19.5	8.0
Omalizumab 75mg	60	14.89	3.53	14.5	8.5	21.0	7.26	6.27	6.8	0.0	21.0	-7.63	6.14	0.79	-8.0	-21.0	7.5
Omalizumab 150mg	57	14.25	3.68	14.0	8.0	21.0	6.06	5.62	5.5	0.0	21.0	-8.19	5.50	0.73	-8.5	-19.0	4.0
Omalizumab 300mg	69	13.96	3.29	13.5	8.0	21.0	3.09	4.68	0.5	0.0	20.5	-10.88	5.28	0.64	-11.5	-19.5	3.5
Week 26																	
Placebo	48	13.53	3.42	14.0	8.0	21.0	5.78	4.32	5.7	0.0	15.0	-7.75	5.10	0.74	-8.3	-21.0	6.0
Omalizumab 75mg	60	15.00	3.52	14.5	8.5	21.0	8.67	6.43	9.3	0.0	21.0	-6.33	6.39	0.82	-6.3	-21.0	9.5
Omalizumab 150mg	53	14.43	3.44	14.0	8.0	21.0	7.29	5.72	7.5	0.0	21.0	-7.15	5.97	0.82	-7.0	-19.5	8.0
Omalizumab 300mg	70	13.85	3.16	13.5	8.0	21.0	3.70	4.90	1.5	0.0	19.5	-10.15	5.57	0.67	-10.8	-19.5	7.5
Week 27																	
Placebo	49	13.66	3.51	14.0	8.0	21.0	6.13	4.38	6.0	0.0	17.5	-7.54	5.06	0.72	-7.0	-21.0	4.0
Omalizumab 75mg	59	15.02	3.55	14.5	8.5	21.0	9.27	6.58	9.0	0.0	21.0	-5.75	6.67	0.87	-5.0	-21.0	10.0
Omalizumab 150mg	52	14.28	3.53	14.0	8.0	21.0	7.31	5.84	7.0	0.0	21.0	-6.97	5.94	0.82	-6.8	-18.5	5.0
Omalizumab 300mg	67	13.96	3.19	14.0	8.0	21.0	4.40	5.30	2.0	0.0	20.5	-9.56	5.59	0.68	-10.5	-19.0	2.0
Week 28																	
Placebo	49	13.66	3.51	14.0	8.0	21.0	5.98	4.35	6.5	0.0	15.5	-7.68	5.10	0.73	-8.0	-21.0	4.0
Omalizumab 75mg	56	14.97	3.58	14.5	8.5	21.0	9.35	6.77	9.0	0.0	21.0	-5.62	6.68	0.89	-5.3	-21.0	10.0
Omalizumab 150mg	51	14.22	3.53	14.0	8.0	21.0	7.79	5.91	7.5	0.0	21.0	-6.43	5.89	0.83	-6.5	-18.5	8.5
Omalizumab 300mg	67	13.83	3.09	13.5	8.0	21.0	4.96	5.38	4.0	0.0	20.1	-8.87	5.45	0.67	-10.0	-19.0	3.0
Week 29																	
Placebo	47	13.57	3.53	14.0	8.0	21.0	5.75	4.64	7.0	0.0	16.5	-7.82	5.11	0.74	-8.5	-21.0	4.0
Omalizumab 75mg	56	14.98	3.62	14.5	8.5	21.0	8.85	6.69	8.5	0.0	21.0	-6.13	6.55	0.88	-5.8	-21.0	10.0
Omalizumab 150mg	51	14.43	3.68	14.0	8.0	21.0	7.99	6.29	8.5	0.0	21.0	-6.45	6.74	0.94	-7.5	-19.0	7.0
Omalizumab 300mg	64	13.85	3.09	13.8	8.0	21.0	5.58	5.37	5.5	0.0	19.5	-8.28	5.24	0.66	-8.3	-19.0	2.0

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 30																	
Placebo	46	13.43	3.43	14.0	8.0	21.0	5.59	4.29	6.8	0.0	14.5	-7.84	5.06	0.75	-7.0	-21.0	3.0
Omalizumab 75mg	54	15.01	3.69	14.5	8.5	21.0	8.73	6.53	7.5	0.0	21.0	-6.28	6.41	0.87	-5.8	-21.0	11.0
Omalizumab 150mg	51	14.43	3.68	14.0	8.0	21.0	7.77	6.39	7.5	0.0	21.0	-6.66	6.74	0.94	-7.5	-18.5	6.5
Omalizumab 300mg	62	13.89	3.11	13.8	8.0	21.0	6.45	6.12	6.3	0.0	21.0	-7.43	5.97	0.76	-7.8	-19.0	3.0
Week 31																	
Placebo	45	13.29	3.32	14.0	8.0	21.0	5.96	5.06	6.5	0.0	17.5	-7.33	5.84	0.87	-8.5	-21.0	7.5
Omalizumab 75mg	52	15.00	3.72	14.5	8.5	21.0	9.20	6.66	9.0	0.0	21.0	-5.80	6.74	0.93	-5.5	-21.0	11.0
Omalizumab 150mg	51	14.43	3.68	14.0	8.0	21.0	8.05	5.91	7.5	0.0	21.0	-6.38	5.77	0.81	-7.5	-16.0	6.5
Omalizumab 300mg	60	13.86	3.10	13.8	8.0	21.0	6.85	6.18	6.8	0.0	21.0	-7.01	6.04	0.78	-7.3	-19.0	5.5
Week 32																	
Placebo	45	13.29	3.32	14.0	8.0	21.0	6.00	5.14	5.5	0.0	17.0	-7.29	5.77	0.86	-8.0	-21.0	4.5
Omalizumab 75mg	51	14.94	3.73	14.5	8.5	21.0	8.89	6.58	7.5	0.0	21.0	-6.05	6.87	0.96	-6.5	-21.0	11.0
Omalizumab 150mg	50	14.46	3.71	14.0	8.0	21.0	7.52	6.01	7.8	0.0	21.0	-6.94	6.40	0.90	-7.8	-17.5	5.5
Omalizumab 300mg	58	13.97	3.09	14.0	8.0	21.0	7.59	6.65	7.0	0.0	21.0	-6.38	6.49	0.85	-6.3	-19.0	8.5
Week 33																	
Placebo	45	13.29	3.32	14.0	8.0	21.0	5.76	5.39	5.5	0.0	20.0	-7.52	6.20	0.92	-7.5	-21.0	5.0
Omalizumab 75mg	50	14.92	3.77	14.5	8.5	21.0	9.05	6.51	9.0	0.0	21.0	-5.87	6.12	0.87	-5.0	-21.0	9.5
Omalizumab 150mg	50	14.50	3.69	14.0	8.0	21.0	8.45	6.43	8.8	0.0	21.0	-6.05	5.93	0.84	-6.5	-17.0	7.0
Omalizumab 300mg	56	13.94	3.13	13.8	8.0	21.0	7.92	6.65	7.0	0.0	21.0	-6.02	6.68	0.89	-6.0	-19.0	8.5
Week 34																	
Placebo	47	13.53	3.46	14.0	8.0	21.0	5.93	5.51	5.8	0.0	20.0	-7.60	6.23	0.91	-8.0	-21.0	5.5
Omalizumab 75mg	49	15.00	3.76	14.5	8.5	21.0	8.40	6.10	7.5	0.0	21.0	-6.60	6.24	0.89	-6.0	-21.0	8.0
Omalizumab 150mg	50	14.46	3.71	14.0	8.0	21.0	7.98	6.02	7.8	0.0	21.0	-6.48	5.68	0.80	-7.0	-16.5	5.5
Omalizumab 300mg	54	13.91	3.17	13.8	8.0	21.0	8.13	6.58	7.8	0.0	21.0	-5.77	6.48	0.88	-5.4	-19.0	4.5
Week 35																	
Placebo	45	13.60	3.51	14.0	8.0	21.0	5.94	5.54	5.5	0.0	20.0	-7.66	6.03	0.90	-8.5	-21.0	3.0
Omalizumab 75mg	48	15.05	3.79	14.5	8.5	21.0	8.99	6.33	9.5	0.0	21.0	-6.06	5.98	0.86	-5.8	-21.0	6.0
Omalizumab 150mg	51	14.43	3.68	14.0	8.0	21.0	7.86	6.02	8.5	0.0	21.0	-6.57	5.61	0.79	-7.0	-17.0	5.5
Omalizumab 300mg	56	13.94	3.13	13.8	8.0	21.0	8.09	6.15	7.3	0.0	21.0	-5.85	6.38	0.85	-6.0	-19.0	7.5

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/3.2
Mean and Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 36																	
Placebo	46	13.63	3.43	14.0	8.0	21.0	5.78	5.68	5.8	0.0	21.0	-7.85	5.80	0.86	-8.3	-21.0	3.5
Omalizumab 75mg	48	15.05	3.79	14.5	8.5	21.0	8.63	6.39	8.8	0.0	21.0	-6.42	6.24	0.90	-5.0	-21.0	4.0
Omalizumab 150mg	51	14.43	3.68	14.0	8.0	21.0	8.22	6.35	8.5	0.0	21.0	-6.21	5.84	0.82	-6.0	-17.0	6.5
Omalizumab 300mg	56	13.94	3.13	13.8	8.0	21.0	7.89	6.35	7.5	0.0	21.0	-6.05	6.44	0.86	-6.0	-19.0	8.0
Week 37																	
Placebo	45	13.59	3.46	14.0	8.0	21.0	6.02	5.69	6.0	0.0	21.0	-7.57	5.82	0.87	-7.5	-21.0	3.5
Omalizumab 75mg	50	15.06	3.75	14.5	8.5	21.0	8.35	6.02	8.5	0.0	21.0	-6.71	5.68	0.80	-5.8	-21.0	3.0
Omalizumab 150mg	50	14.55	3.62	14.0	8.0	21.0	8.12	6.72	8.5	0.0	21.0	-6.43	6.15	0.87	-7.5	-20.0	6.0
Omalizumab 300mg	51	13.98	3.24	14.0	8.0	21.0	8.51	6.56	7.5	0.0	21.0	-5.47	6.60	0.92	-5.0	-19.0	8.0
Week 38																	
Placebo	44	13.44	3.36	14.0	8.0	21.0	5.42	5.65	4.5	0.0	21.0	-8.02	5.93	0.89	-8.8	-21.0	3.5
Omalizumab 75mg	48	15.08	3.82	14.5	8.5	21.0	7.84	6.50	7.0	0.0	21.0	-7.24	6.16	0.89	-8.0	-21.0	4.0
Omalizumab 150mg	50	14.55	3.62	14.0	8.0	21.0	8.05	6.78	8.0	0.0	21.0	-6.50	6.37	0.90	-7.0	-21.0	8.5
Omalizumab 300mg	52	13.96	3.21	14.0	8.0	21.0	8.65	6.66	7.3	0.0	21.0	-5.31	6.71	0.93	-4.5	-19.0	6.5
Week 39																	
Placebo	45	13.59	3.46	14.0	8.0	21.0	6.00	5.87	5.5	0.0	20.0	-7.59	5.97	0.89	-8.0	-18.5	4.5
Omalizumab 75mg	47	15.01	3.76	14.5	8.5	21.0	7.99	6.53	7.5	0.0	21.0	-7.02	6.23	0.91	-7.0	-21.0	4.0
Omalizumab 150mg	49	14.42	3.53	14.0	8.0	21.0	7.96	6.62	7.5	0.0	21.0	-6.46	6.25	0.89	-8.0	-17.0	10.8
Omalizumab 300mg	50	13.87	3.17	14.0	8.0	21.0	8.07	6.50	7.0	0.0	21.0	-5.80	6.68	0.94	-5.3	-19.0	7.0
Week 40																	
Placebo	41	13.54	3.51	14.0	8.0	21.0	5.91	5.58	5.0	0.0	16.0	-7.63	6.03	0.94	-9.0	-18.5	4.0
Omalizumab 75mg	46	14.88	3.70	14.5	8.5	21.0	7.84	6.64	7.0	0.0	21.0	-7.05	6.36	0.94	-7.5	-21.0	3.0
Omalizumab 150mg	49	14.57	3.65	14.0	8.0	21.0	8.08	6.85	7.0	0.0	21.0	-6.50	6.47	0.92	-8.0	-17.0	11.5
Omalizumab 300mg	47	13.84	3.24	14.0	8.0	21.0	8.30	6.56	7.0	0.0	21.0	-5.54	6.94	1.01	-6.0	-19.0	9.9

* Number of subjects with both baseline and visit values.
Baseline weekly itch severity score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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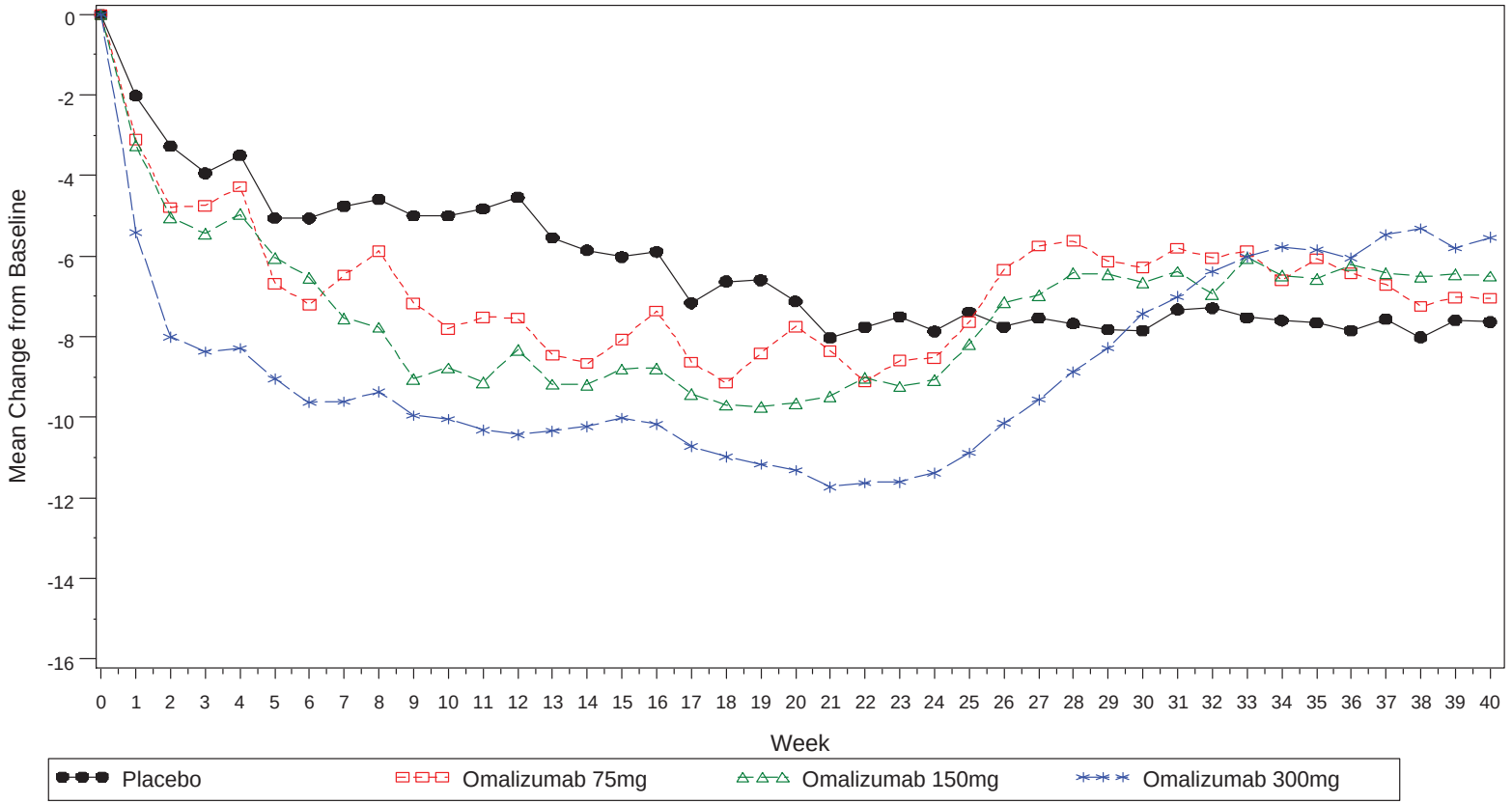
Figure 14.2/1.3
Mean Change from Baseline in Weekly Itch Severity Score by Study Week (Observed Data)
Modified Intention to Treat Patients



Number of Patients

Placebo	80	73	67	64	59	55	55	49	45	46	41
Omalizumab 75mg	77	71	68	66	66	61	63	56	51	48	46
Omalizumab 150mg	80	76	69	64	61	61	57	51	50	51	49
Omalizumab 300mg	81	76	73	73	71	68	70	67	58	56	47

Missing weekly scores are not imputed.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Baseline																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	31.10	6.67	31.5	16.0	42.0						
Omalizumab 75mg	77	31.69	6.69	31.5	17.0	42.0	31.69	6.69	31.5	17.0	42.0						
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	30.26	7.26	30.8	16.0	42.0						
Omalizumab 300mg	81	31.32	5.79	31.5	19.5	42.0	31.32	5.79	31.5	19.5	42.0						
Week 1																	
Placebo	80	31.10	6.67	31.5	16.0	42.0	27.07	8.25	28.0	8.5	42.0	-4.03	6.68	0.75	-3.0	-21.5	14.5
Omalizumab 75mg	76	31.74	6.72	31.8	17.0	42.0	25.59	8.85	27.3	6.5	42.0	-6.15	8.14	0.93	-4.3	-24.0	11.5
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	24.00	9.97	24.8	0.5	42.0	-6.26	8.95	1.00	-4.5	-33.0	12.5
Omalizumab 300mg	80	31.26	5.80	31.0	19.5	42.0	19.98	9.31	20.5	2.0	38.0	-11.29	8.72	0.98	-10.8	-33.5	3.5
Week 2																	
Placebo	77	30.98	6.55	31.5	16.0	42.0	24.42	10.37	26.5	0.0	39.5	-6.56	9.71	1.11	-4.0	-32.0	13.1
Omalizumab 75mg	75	31.61	6.67	31.5	17.0	42.0	21.69	12.17	22.5	0.0	42.0	-9.92	11.48	1.33	-8.5	-38.5	9.0
Omalizumab 150mg	80	30.26	7.26	30.8	16.0	42.0	19.70	12.20	17.8	0.0	42.0	-10.57	11.42	1.28	-9.8	-39.5	8.0
Omalizumab 300mg	78	31.01	5.65	30.5	19.5	42.0	13.28	11.23	13.5	0.0	38.0	-17.74	11.63	1.32	-15.8	-42.0	0.5
Week 3																	
Placebo	77	30.98	6.55	31.5	16.0	42.0	23.09	9.91	25.0	0.0	41.0	-7.89	9.44	1.08	-6.0	-31.5	10.0
Omalizumab 75mg	73	31.49	6.68	31.5	17.0	42.0	21.55	11.17	22.0	0.0	42.0	-9.94	10.17	1.19	-8.5	-36.5	7.0
Omalizumab 150mg	79	30.23	7.30	30.5	16.0	42.0	18.77	12.55	19.0	0.0	42.0	-11.46	11.90	1.34	-9.0	-38.5	9.5
Omalizumab 300mg	78	31.01	5.65	30.5	19.5	42.0	12.60	11.88	9.5	0.0	38.0	-18.41	12.58	1.42	-18.8	-41.0	10.0
Week 4																	
Placebo	73	30.85	6.44	31.5	16.0	42.0	23.79	10.26	26.3	0.0	42.0	-7.06	9.24	1.08	-4.5	-31.5	13.0
Omalizumab 75mg	71	31.49	6.69	31.5	17.0	42.0	22.61	11.91	25.0	0.0	42.0	-8.88	10.90	1.29	-5.5	-36.5	11.0
Omalizumab 150mg	76	30.30	7.26	30.8	16.0	42.0	20.28	13.18	20.7	0.0	42.0	-10.01	11.96	1.37	-8.3	-40.0	16.0
Omalizumab 300mg	76	31.18	5.60	31.0	19.5	42.0	13.03	12.09	11.8	0.0	39.0	-18.15	12.48	1.43	-18.3	-40.0	10.0
Week 5																	
Placebo	69	30.78	6.60	31.5	16.0	42.0	20.82	11.37	23.6	0.0	38.0	-9.96	11.17	1.35	-6.8	-37.0	9.0
Omalizumab 75mg	65	31.72	6.68	31.5	17.0	42.0	18.18	11.97	16.3	0.0	42.0	-13.54	11.88	1.47	-10.5	-40.3	8.0
Omalizumab 150mg	69	29.79	7.05	30.5	16.0	42.0	16.84	12.47	13.5	0.0	42.0	-12.95	12.86	1.55	-10.0	-40.0	15.8
Omalizumab 300mg	74	31.03	5.77	31.0	19.5	42.0	10.99	11.74	8.9	0.0	40.0	-20.04	12.05	1.40	-21.0	-40.0	11.0

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 6																	
Placebo	70	30.55	6.41	31.0	16.0	42.0	20.18	11.73	22.3	0.0	38.5	-10.37	11.52	1.38	-7.3	-39.0	6.5
Omalizumab 75mg	72	31.44	6.71	31.5	17.0	42.0	16.65	11.93	14.9	0.0	42.0	-14.79	12.36	1.46	-14.5	-40.5	9.0
Omalizumab 150mg	75	30.20	7.19	30.5	16.0	42.0	16.28	13.13	14.6	0.0	42.0	-13.92	12.90	1.49	-13.5	-40.0	10.0
Omalizumab 300mg	75	31.01	5.73	30.5	19.5	42.0	9.78	10.79	7.0	0.0	36.2	-21.24	11.05	1.28	-21.5	-42.0	2.0
Week 7																	
Placebo	69	30.43	6.38	31.0	16.0	42.0	20.74	10.89	23.0	0.0	38.5	-9.70	11.25	1.35	-5.8	-37.0	11.0
Omalizumab 75mg	72	31.44	6.71	31.5	17.0	42.0	17.58	12.89	16.8	0.0	42.0	-13.87	12.28	1.45	-13.8	-41.0	8.5
Omalizumab 150mg	73	30.03	7.22	30.5	16.0	42.0	13.72	12.58	11.5	0.0	42.0	-16.31	12.71	1.49	-16.0	-40.0	8.0
Omalizumab 300mg	76	31.00	5.70	30.5	19.5	42.0	9.84	11.14	4.0	0.0	36.5	-21.16	11.97	1.37	-23.3	-42.0	5.0
Week 8																	
Placebo	67	30.22	6.33	30.5	16.0	42.0	20.93	11.11	23.9	0.0	39.5	-9.30	11.22	1.37	-6.5	-39.0	11.0
Omalizumab 75mg	68	31.63	6.56	31.5	17.0	42.0	19.22	13.22	19.5	0.0	42.0	-12.40	12.54	1.52	-11.8	-42.0	9.5
Omalizumab 150mg	69	30.11	7.16	30.5	16.0	42.0	13.74	13.09	9.0	0.0	42.0	-16.36	12.91	1.55	-17.5	-40.0	11.0
Omalizumab 300mg	73	31.10	5.69	30.5	19.5	42.0	9.89	11.51	4.0	0.0	37.6	-21.22	12.24	1.43	-23.0	-40.3	11.1
Week 9																	
Placebo	60	30.09	6.47	30.8	16.0	42.0	19.24	12.36	22.9	0.0	38.0	-10.85	12.35	1.59	-8.8	-39.0	12.5
Omalizumab 75mg	62	31.99	6.89	32.5	17.0	42.0	17.26	12.35	16.0	0.0	42.0	-14.73	12.63	1.60	-14.5	-42.0	8.5
Omalizumab 150mg	61	30.48	7.11	31.0	16.0	42.0	11.45	11.77	6.5	0.0	35.0	-19.03	11.79	1.51	-19.5	-40.0	4.0
Omalizumab 300mg	68	30.90	5.70	30.3	19.5	42.0	8.71	10.07	4.4	0.0	35.5	-22.19	10.35	1.26	-22.3	-42.0	7.0
Week 10																	
Placebo	64	30.31	6.26	30.8	16.0	42.0	20.01	11.15	21.8	0.0	39.5	-10.30	11.85	1.48	-8.0	-37.5	17.0
Omalizumab 75mg	68	31.71	6.66	31.8	17.0	42.0	15.58	12.26	13.8	0.0	42.0	-16.13	13.00	1.58	-16.0	-42.0	7.0
Omalizumab 150mg	67	29.74	7.25	30.5	16.0	42.0	10.75	10.77	7.5	0.0	38.5	-18.99	11.94	1.46	-20.5	-42.0	5.5
Omalizumab 300mg	74	31.05	5.76	31.0	19.5	42.0	8.49	10.76	3.0	0.0	39.2	-22.56	11.81	1.37	-25.5	-42.0	4.5
Week 11																	
Placebo	64	30.24	6.33	30.8	16.0	42.0	20.06	11.61	22.8	0.0	42.0	-10.18	11.60	1.45	-9.0	-39.0	14.3
Omalizumab 75mg	68	31.71	6.66	31.8	17.0	42.0	15.71	12.19	13.8	0.0	42.0	-16.00	12.55	1.52	-16.5	-42.0	7.0
Omalizumab 150mg	66	29.67	7.28	30.5	16.0	42.0	9.97	10.58	5.5	0.0	36.0	-19.70	12.13	1.49	-20.5	-42.0	4.0
Omalizumab 300mg	74	31.05	5.76	31.0	19.5	42.0	8.10	10.03	2.5	0.0	39.0	-22.95	11.28	1.31	-24.5	-42.0	8.5

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 12																	
Placebo	64	30.24	6.33	30.8	16.0	42.0	20.24	12.01	22.0	0.0	41.0	-10.01	12.02	1.50	-7.8	-39.0	14.5
Omalizumab 75mg	66	31.98	6.50	32.3	17.0	42.0	15.86	12.61	14.8	0.0	42.0	-16.13	12.95	1.59	-16.2	-42.0	7.0
Omalizumab 150mg	64	29.45	7.22	30.5	16.0	42.0	11.41	11.33	7.0	0.0	37.0	-18.04	12.01	1.50	-18.8	-40.0	4.5
Omalizumab 300mg	73	30.98	5.79	30.5	19.5	42.0	7.96	9.74	2.5	0.0	40.3	-23.02	10.56	1.24	-24.5	-40.0	1.0
Week 13																	
Placebo	50	29.49	6.57	30.5	16.0	42.0	17.46	10.92	17.8	0.0	38.5	-12.03	12.09	1.71	-10.3	-39.0	13.0
Omalizumab 75mg	61	32.07	6.63	32.5	17.0	42.0	14.14	12.56	13.0	0.0	42.0	-17.93	12.66	1.62	-18.6	-42.0	4.5
Omalizumab 150mg	57	30.59	6.97	30.5	16.0	42.0	10.56	10.78	6.0	0.0	33.8	-20.03	11.50	1.52	-20.0	-40.0	4.7
Omalizumab 300mg	68	31.05	5.77	31.0	19.5	42.0	7.86	10.44	2.1	0.0	39.2	-23.19	11.24	1.36	-24.5	-41.0	3.0
Week 14																	
Placebo	60	30.16	6.37	30.5	16.0	42.0	17.16	11.06	17.3	0.0	42.0	-13.00	12.28	1.59	-12.5	-39.0	19.5
Omalizumab 75mg	66	32.03	6.46	32.3	17.0	42.0	13.55	13.61	10.3	0.0	42.0	-18.48	13.50	1.66	-20.0	-42.0	7.0
Omalizumab 150mg	63	29.71	7.37	30.5	16.0	42.0	9.46	9.55	5.5	0.0	32.0	-20.25	10.81	1.36	-20.0	-39.5	1.0
Omalizumab 300mg	72	30.85	5.73	30.3	19.5	42.0	7.73	10.60	2.5	0.0	37.5	-23.12	11.38	1.34	-25.5	-40.0	8.5
Week 15																	
Placebo	59	30.29	6.34	30.5	16.0	42.0	16.87	10.98	16.5	0.0	38.5	-13.42	11.92	1.55	-12.5	-39.0	14.0
Omalizumab 75mg	65	31.95	6.48	32.0	17.0	42.0	14.59	13.98	13.0	0.0	42.0	-17.35	14.15	1.75	-20.0	-42.0	7.5
Omalizumab 150mg	63	29.71	7.37	30.5	16.0	42.0	10.27	10.44	8.0	0.0	35.0	-19.44	11.55	1.46	-19.0	-39.5	4.0
Omalizumab 300mg	71	30.90	5.76	30.5	19.5	42.0	8.19	11.66	2.5	0.0	41.1	-22.71	12.38	1.47	-26.5	-40.0	11.0
Week 16																	
Placebo	59	30.29	6.34	30.5	16.0	42.0	17.02	11.43	14.0	0.0	41.0	-13.27	12.14	1.58	-14.8	-39.0	9.0
Omalizumab 75mg	66	31.84	6.48	31.8	17.0	42.0	15.92	14.30	12.0	0.0	42.0	-15.92	14.30	1.76	-16.5	-42.0	13.0
Omalizumab 150mg	61	29.62	7.47	30.5	16.0	42.0	10.55	10.66	8.5	0.0	36.8	-19.07	11.00	1.41	-17.0	-40.0	3.0
Omalizumab 300mg	71	30.98	5.67	30.5	19.5	42.0	7.92	10.94	1.4	0.0	41.1	-23.06	11.50	1.36	-25.5	-40.0	3.0
Week 17																	
Placebo	55	30.28	6.42	30.5	16.0	42.0	14.55	10.92	14.0	0.0	38.5	-15.73	11.53	1.55	-14.0	-39.0	8.9
Omalizumab 75mg	59	31.79	6.47	32.0	17.0	42.0	13.52	13.67	8.5	0.0	42.0	-18.27	13.91	1.81	-20.5	-42.0	14.0
Omalizumab 150mg	57	29.95	7.74	30.5	16.0	42.0	9.55	11.15	4.7	0.0	39.0	-20.40	11.95	1.58	-19.5	-40.0	8.2
Omalizumab 300mg	65	30.65	5.76	30.5	19.5	42.0	6.16	9.05	1.2	0.0	41.0	-24.49	9.90	1.23	-26.5	-39.0	-1.0

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 18																	
Placebo	57	29.94	6.32	30.5	16.0	42.0	15.56	10.63	15.0	0.0	39.0	-14.38	11.46	1.52	-13.5	-35.0	13.5
Omalizumab 75mg	64	32.19	6.47	32.5	17.0	42.0	12.58	14.01	7.0	0.0	42.0	-19.61	13.93	1.74	-21.8	-42.0	14.0
Omalizumab 150mg	62	29.71	7.51	30.5	16.0	42.0	8.89	8.99	5.8	0.0	31.0	-20.82	10.86	1.38	-20.5	-42.0	0.0
Omalizumab 300mg	71	30.90	5.76	30.5	19.5	42.0	6.05	8.77	1.5	0.0	41.5	-24.85	9.80	1.16	-26.5	-40.0	1.0
Week 19																	
Placebo	57	29.98	6.37	30.5	16.0	42.0	15.87	11.45	14.0	0.0	42.0	-14.12	11.90	1.58	-14.0	-35.0	16.5
Omalizumab 75mg	64	32.19	6.47	32.5	17.0	42.0	14.30	14.13	9.8	0.0	42.0	-17.88	14.01	1.75	-19.8	-42.0	9.0
Omalizumab 150mg	62	29.71	7.51	30.5	16.0	42.0	8.96	9.59	5.0	0.0	32.5	-20.75	10.95	1.39	-20.0	-42.0	2.0
Omalizumab 300mg	72	30.85	5.73	30.3	19.5	42.0	5.50	8.75	1.1	0.0	40.6	-25.35	9.58	1.13	-27.4	-40.0	-1.0
Week 20																	
Placebo	55	30.04	6.40	30.5	16.0	42.0	14.71	11.51	14.0	0.0	42.0	-15.33	12.10	1.63	-15.5	-36.0	12.1
Omalizumab 75mg	61	31.97	6.55	32.0	17.0	42.0	15.35	14.31	13.0	0.0	42.0	-16.62	13.66	1.75	-15.3	-42.0	9.5
Omalizumab 150mg	61	29.64	7.55	30.5	16.0	42.0	9.06	9.40	6.5	0.0	35.0	-20.58	10.75	1.38	-21.0	-40.0	7.0
Omalizumab 300mg	68	31.00	5.77	31.0	19.5	42.0	5.32	8.95	1.0	0.0	41.0	-25.68	9.21	1.12	-27.0	-40.0	-1.0
Week 21																	
Placebo	50	30.29	6.27	30.5	16.0	42.0	12.91	10.95	9.4	0.0	35.0	-17.38	11.82	1.67	-20.5	-37.3	9.5
Omalizumab 75mg	59	32.30	6.59	32.5	17.0	42.0	14.63	13.38	13.5	0.0	42.0	-17.67	13.15	1.71	-20.0	-42.0	8.0
Omalizumab 150mg	52	30.76	6.95	30.8	16.0	42.0	9.94	10.04	7.3	0.0	37.8	-20.82	10.84	1.50	-22.5	-42.0	7.0
Omalizumab 300mg	67	31.10	5.70	30.5	19.5	42.0	4.76	8.08	0.0	0.0	41.3	-26.34	9.13	1.12	-27.5	-40.0	-0.7
Week 22																	
Placebo	55	29.95	6.25	30.5	16.0	42.0	13.12	10.97	11.5	0.0	41.5	-16.83	11.93	1.61	-19.0	-36.0	16.0
Omalizumab 75mg	64	32.25	6.54	32.5	17.0	42.0	12.55	12.98	9.0	0.0	42.0	-19.70	13.07	1.63	-21.5	-42.0	9.5
Omalizumab 150mg	58	30.09	7.40	30.5	16.0	42.0	10.75	11.95	5.8	0.0	42.0	-19.34	12.72	1.67	-18.8	-42.0	7.0
Omalizumab 300mg	70	30.94	5.70	30.3	19.5	42.0	4.61	8.34	0.0	0.0	41.3	-26.32	9.13	1.09	-27.5	-40.0	-0.7
Week 23																	
Placebo	56	30.10	6.30	30.5	16.0	42.0	13.97	11.49	11.5	0.0	40.5	-16.13	12.39	1.66	-17.3	-36.0	15.5
Omalizumab 75mg	63	32.35	6.54	32.5	17.0	42.0	13.73	13.79	9.0	0.0	42.0	-18.62	13.62	1.72	-20.0	-42.0	8.5
Omalizumab 150mg	58	29.68	7.38	30.5	16.0	42.0	9.51	10.03	7.3	0.0	35.5	-20.17	11.94	1.57	-20.5	-41.0	7.0
Omalizumab 300mg	71	30.81	5.76	30.0	19.5	42.0	4.52	8.36	0.0	0.0	42.0	-26.29	9.09	1.08	-28.0	-40.0	0.0

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 24																	
Placebo	55	30.08	6.36	30.5	16.0	42.0	13.02	11.31	10.5	0.0	40.0	-17.06	11.71	1.58	-17.5	-42.0	11.5
Omalizumab 75mg	63	32.35	6.54	32.5	17.0	42.0	14.11	13.68	11.5	0.0	42.0	-18.24	13.08	1.65	-20.0	-42.0	7.0
Omalizumab 150mg	57	29.67	7.44	30.5	16.0	42.0	9.72	10.67	5.0	0.0	41.5	-19.95	11.59	1.53	-21.6	-40.0	10.5
Omalizumab 300mg	70	30.69	5.72	30.0	19.5	42.0	5.10	8.86	0.0	0.0	40.8	-25.59	9.48	1.13	-27.8	-40.0	-1.2
Week 25																	
Placebo	52	30.03	6.53	30.5	16.0	42.0	13.72	10.58	12.6	0.0	40.0	-16.31	11.84	1.64	-17.4	-39.0	14.5
Omalizumab 75mg	60	32.18	6.58	32.5	17.0	42.0	15.72	13.37	14.0	0.0	42.0	-16.46	12.66	1.63	-15.9	-42.0	7.5
Omalizumab 150mg	57	30.07	7.46	30.5	16.0	42.0	12.30	11.50	10.5	0.0	42.0	-17.77	11.01	1.46	-18.0	-39.5	3.0
Omalizumab 300mg	69	30.82	5.66	30.0	19.5	42.0	5.97	9.54	1.0	0.0	41.5	-24.84	10.24	1.23	-27.5	-39.0	1.0
Week 26																	
Placebo	48	29.92	6.46	30.5	16.0	42.0	13.02	10.17	13.0	0.0	36.0	-16.90	11.47	1.66	-17.3	-42.0	14.0
Omalizumab 75mg	60	32.43	6.49	32.5	17.0	42.0	18.65	13.74	17.8	0.0	42.0	-13.78	13.26	1.71	-12.0	-42.0	10.0
Omalizumab 150mg	53	30.32	7.13	30.5	16.0	42.0	14.89	11.83	13.0	0.0	42.0	-15.43	11.77	1.62	-16.0	-39.5	9.0
Omalizumab 300mg	70	30.58	5.56	30.0	19.5	42.0	7.43	10.01	3.3	0.0	40.5	-23.15	10.95	1.31	-25.5	-39.0	7.5
Week 27																	
Placebo	49	30.09	6.51	30.5	16.0	42.0	13.92	10.48	14.0	0.0	37.3	-16.17	11.87	1.70	-14.0	-42.0	13.0
Omalizumab 75mg	59	32.42	6.55	32.5	17.0	42.0	19.67	13.86	18.5	0.0	42.0	-12.75	13.33	1.74	-13.5	-42.0	10.5
Omalizumab 150mg	52	30.13	7.12	30.5	16.0	42.0	15.08	12.19	13.8	0.0	42.0	-15.06	11.56	1.60	-13.5	-39.5	6.0
Omalizumab 300mg	67	30.92	5.40	30.5	20.5	42.0	8.83	10.62	4.0	0.0	41.5	-22.09	10.95	1.34	-25.0	-39.0	2.0
Week 28																	
Placebo	49	30.08	6.49	30.5	16.0	42.0	12.93	9.80	12.3	0.0	34.5	-17.15	11.50	1.64	-16.0	-42.0	9.5
Omalizumab 75mg	56	32.35	6.58	32.5	17.0	42.0	20.09	13.90	20.8	0.0	42.0	-12.25	13.36	1.79	-9.8	-41.5	10.5
Omalizumab 150mg	51	30.13	7.19	30.5	16.0	42.0	16.14	12.34	15.0	0.0	42.0	-13.99	11.44	1.60	-13.0	-39.5	9.5
Omalizumab 300mg	67	30.63	5.36	30.0	20.5	42.0	10.33	11.37	6.0	0.0	41.1	-20.30	11.33	1.38	-22.0	-39.0	3.0
Week 29																	
Placebo	47	29.89	6.51	30.5	16.0	42.0	12.52	10.14	12.0	0.0	31.0	-17.38	11.63	1.70	-18.0	-42.0	10.0
Omalizumab 75mg	56	32.38	6.61	32.5	17.0	42.0	19.87	13.68	19.5	0.0	42.0	-12.51	12.92	1.73	-10.8	-41.5	10.5
Omalizumab 150mg	51	30.36	7.34	30.5	16.0	42.0	16.82	13.27	18.0	0.0	42.0	-13.54	13.46	1.89	-14.0	-39.5	7.5
Omalizumab 300mg	64	30.63	5.23	30.0	20.5	42.0	11.67	11.18	10.3	0.0	40.5	-18.95	11.16	1.40	-19.5	-38.5	2.5

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 30																	
Placebo	46	29.67	6.41	30.5	16.0	42.0	12.11	9.82	13.3	0.0	28.5	-17.57	11.31	1.67	-14.3	-42.0	8.0
Omalizumab 75mg	54	32.39	6.71	32.5	17.0	42.0	19.06	13.24	18.8	0.0	42.0	-13.33	12.83	1.75	-10.3	-38.0	14.0
Omalizumab 150mg	51	30.36	7.34	30.5	16.0	42.0	16.25	13.29	14.0	0.0	42.0	-14.12	13.61	1.91	-13.5	-39.5	9.0
Omalizumab 300mg	62	30.63	5.28	30.0	20.5	42.0	14.05	12.64	13.3	0.0	42.0	-16.58	12.73	1.62	-16.5	-37.5	7.5
Week 31																	
Placebo	45	29.48	6.34	30.5	16.0	42.0	13.11	11.30	11.0	0.0	35.0	-16.37	12.87	1.92	-18.0	-42.0	17.5
Omalizumab 75mg	52	32.27	6.80	32.3	17.0	42.0	20.12	13.54	20.0	0.0	42.0	-12.15	12.93	1.79	-11.3	-37.0	14.0
Omalizumab 150mg	51	30.36	7.34	30.5	16.0	42.0	16.58	12.00	15.0	0.0	42.0	-13.79	11.59	1.62	-16.0	-36.0	7.5
Omalizumab 300mg	60	30.51	5.25	30.0	20.5	42.0	14.51	12.99	13.5	0.0	42.0	-16.00	13.06	1.69	-17.8	-37.5	11.5
Week 32																	
Placebo	45	29.48	6.34	30.5	16.0	42.0	13.54	11.53	12.5	0.0	37.5	-15.94	12.87	1.92	-17.0	-42.0	7.6
Omalizumab 75mg	51	32.14	6.80	32.0	17.0	42.0	19.45	13.40	18.0	0.0	42.0	-12.69	13.02	1.82	-11.5	-42.0	14.0
Omalizumab 150mg	50	30.36	7.41	30.5	16.0	42.0	15.96	12.70	14.8	0.0	42.0	-14.40	13.35	1.89	-16.8	-36.5	10.0
Omalizumab 300mg	58	30.59	5.31	30.3	20.5	42.0	15.76	13.86	14.5	0.0	42.0	-14.84	13.77	1.81	-14.5	-38.0	15.0
Week 33																	
Placebo	45	29.48	6.34	30.5	16.0	42.0	12.63	11.60	9.5	0.0	35.5	-16.85	13.47	2.01	-18.0	-42.0	11.0
Omalizumab 75mg	50	32.07	6.85	31.8	17.0	42.0	19.62	12.98	19.8	0.0	42.0	-12.46	11.74	1.66	-12.0	-37.0	12.5
Omalizumab 150mg	50	30.40	7.41	30.5	16.0	42.0	17.43	13.34	16.0	0.0	42.0	-12.97	12.58	1.78	-13.3	-37.5	12.0
Omalizumab 300mg	56	30.41	5.30	30.0	20.5	42.0	16.27	13.79	14.7	0.0	42.0	-14.14	14.35	1.92	-13.6	-37.5	15.0
Week 34																	
Placebo	47	29.86	6.47	30.5	16.0	42.0	12.97	12.13	7.5	0.0	38.0	-16.90	13.50	1.97	-20.0	-42.0	13.5
Omalizumab 75mg	49	32.08	6.92	32.0	17.0	42.0	19.10	12.58	19.0	0.0	42.0	-12.98	12.11	1.73	-11.0	-42.0	11.0
Omalizumab 150mg	50	30.36	7.41	30.5	16.0	42.0	17.07	12.44	16.5	0.0	42.0	-13.29	11.99	1.69	-14.3	-37.5	8.3
Omalizumab 300mg	54	30.44	5.39	30.0	20.5	42.0	16.85	13.91	17.0	0.0	42.0	-13.59	14.37	1.96	-10.0	-38.0	9.0
Week 35																	
Placebo	45	29.73	6.58	30.5	16.0	42.0	13.49	12.33	11.0	0.0	39.0	-16.24	13.51	2.01	-16.0	-42.0	14.5
Omalizumab 75mg	48	32.25	6.89	32.3	17.0	42.0	19.96	12.82	21.0	0.0	42.0	-12.29	11.94	1.72	-9.8	-42.0	9.0
Omalizumab 150mg	51	30.36	7.34	30.5	16.0	42.0	17.05	12.70	15.0	0.0	42.0	-13.32	11.99	1.68	-14.5	-36.5	11.0
Omalizumab 300mg	56	30.41	5.30	30.0	20.5	42.0	17.51	13.15	17.0	0.0	42.0	-12.90	13.96	1.87	-9.8	-38.0	13.0

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/5.2
Mean and Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 36																	
Placebo	46	30.15	6.22	30.5	16.0	42.0	12.79	12.32	10.8	0.0	41.5	-17.37	12.93	1.91	-16.8	-42.0	17.0
Omalizumab 75mg	48	32.25	6.89	32.3	17.0	42.0	19.26	12.98	19.5	0.0	42.0	-12.99	12.41	1.79	-11.0	-42.0	7.0
Omalizumab 150mg	51	30.36	7.34	30.5	16.0	42.0	17.17	13.34	15.5	0.0	42.0	-13.19	12.77	1.79	-14.0	-36.5	12.0
Omalizumab 300mg	56	30.41	5.30	30.0	20.5	42.0	16.79	13.77	16.5	0.0	42.0	-13.62	14.41	1.93	-11.5	-38.0	14.5
Week 37																	
Placebo	45	30.12	6.29	30.5	16.0	42.0	13.19	12.24	14.0	0.0	42.0	-16.93	12.70	1.89	-16.5	-42.0	17.5
Omalizumab 75mg	50	32.19	6.89	32.3	17.0	42.0	19.18	12.53	19.5	0.0	42.0	-13.01	11.47	1.62	-12.3	-42.0	6.0
Omalizumab 150mg	50	30.52	7.33	30.5	16.0	42.0	16.83	13.75	15.0	0.0	42.0	-13.69	12.88	1.82	-16.0	-40.0	12.0
Omalizumab 300mg	51	30.49	5.50	30.0	20.5	42.0	17.97	14.06	17.5	0.0	42.0	-12.52	14.88	2.08	-7.0	-38.0	14.5
Week 38																	
Placebo	44	29.93	6.23	30.5	16.0	42.0	11.91	12.06	10.0	0.0	42.0	-18.02	12.98	1.96	-18.3	-42.0	17.5
Omalizumab 75mg	48	32.31	6.94	32.3	17.0	42.0	17.94	13.32	15.3	0.0	42.0	-14.37	12.54	1.81	-13.8	-42.0	7.0
Omalizumab 150mg	50	30.52	7.33	30.5	16.0	42.0	16.66	13.84	15.0	0.0	42.0	-13.86	13.19	1.87	-16.0	-42.0	15.5
Omalizumab 300mg	52	30.49	5.44	30.0	20.5	42.0	18.14	13.95	19.3	0.0	42.0	-12.35	14.72	2.04	-8.8	-38.0	13.0
Week 39																	
Placebo	45	30.12	6.29	30.5	16.0	42.0	13.20	12.58	10.5	0.0	39.0	-16.92	13.00	1.94	-16.5	-39.0	14.5
Omalizumab 75mg	47	31.99	7.02	32.0	17.0	42.0	17.77	13.28	15.0	0.0	42.0	-14.22	12.59	1.84	-12.0	-42.0	7.0
Omalizumab 150mg	49	30.29	7.21	30.5	16.0	42.0	16.78	13.66	15.5	0.0	42.0	-13.51	13.25	1.89	-17.5	-37.5	20.2
Omalizumab 300mg	50	30.42	5.54	29.5	20.5	42.0	17.03	13.64	17.0	0.0	42.0	-13.39	14.63	2.07	-11.5	-38.0	14.5
Week 40																	
Placebo	41	30.34	6.18	30.5	16.0	42.0	12.73	11.92	10.0	0.0	34.5	-17.61	12.60	1.97	-18.9	-39.0	7.5
Omalizumab 75mg	46	31.77	6.94	31.8	17.0	42.0	17.50	13.44	16.5	0.0	42.0	-14.27	12.60	1.86	-12.8	-42.0	5.0
Omalizumab 150mg	49	30.45	7.39	30.5	16.0	42.0	16.75	13.84	16.5	0.0	42.0	-13.70	13.37	1.91	-18.1	-37.5	21.5
Omalizumab 300mg	47	30.38	5.57	30.0	20.5	42.0	17.54	13.82	19.0	0.0	42.0	-12.84	14.84	2.17	-12.5	-37.5	15.3

* Number of subjects with both baseline and visit values.
Baseline UAS7 is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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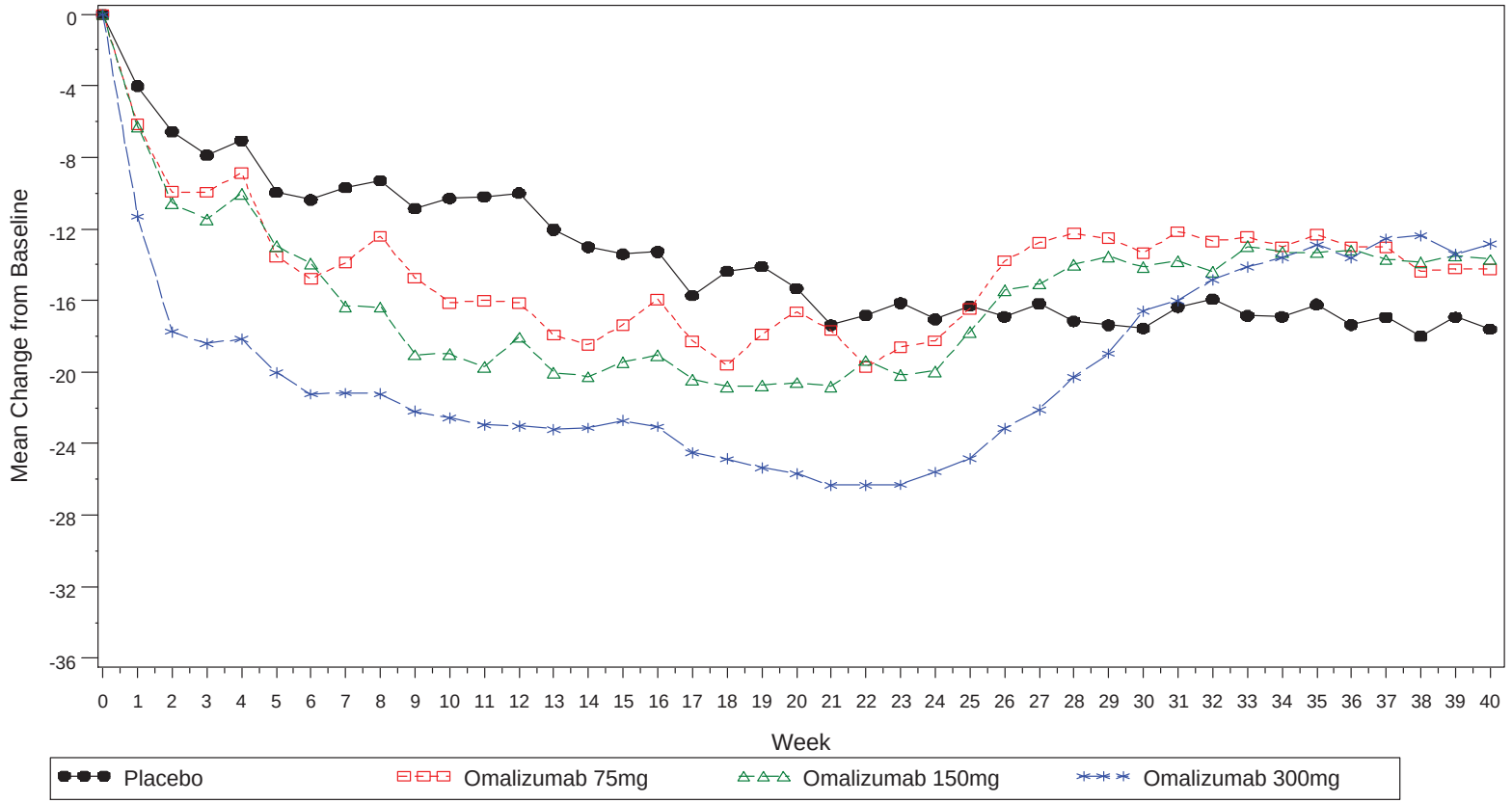
Figure 14.2/2.3
Mean Change from Baseline in UAS7 by Study Week (Observed Data)
Modified Intention to Treat Patients



Number of Patients

Placebo	80	73	67	64	59	55	55	49	45	46	41
Omalizumab 75mg	77	71	68	66	66	61	63	56	51	48	46
Omalizumab 150mg	80	76	69	64	61	61	57	51	50	51	49
Omalizumab 300mg	81	76	73	73	71	68	70	67	58	56	47

Missing weekly scores are not imputed.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Baseline																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	16.73	4.42	18.3	5.0	21.0						
Omalizumab 75mg	77	17.23	4.19	19.0	7.5	21.0	17.23	4.19	19.0	7.5	21.0						
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	16.17	4.61	17.0	4.5	21.0						
Omalizumab 300mg	81	17.12	3.82	18.5	8.5	21.0	17.12	3.82	18.5	8.5	21.0						
Week 1																	
Placebo	80	16.73	4.42	18.3	5.0	21.0	14.73	5.24	15.0	3.5	21.0	-2.00	3.87	0.43	-1.0	-13.0	8.5
Omalizumab 75mg	76	17.20	4.21	19.0	7.5	21.0	14.15	5.53	14.5	1.5	21.0	-3.04	4.65	0.53	-2.0	-17.0	6.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	13.15	5.93	14.0	0.0	21.0	-3.02	5.07	0.57	-2.0	-19.0	8.0
Omalizumab 300mg	80	17.08	3.82	18.3	8.5	21.0	11.19	5.68	10.5	1.0	21.0	-5.88	4.84	0.54	-5.0	-16.5	3.0
Week 2																	
Placebo	77	16.69	4.41	18.0	5.0	21.0	13.39	6.15	14.0	0.0	21.0	-3.29	5.41	0.62	-1.5	-17.5	8.0
Omalizumab 75mg	75	17.15	4.21	19.0	7.5	21.0	12.01	7.14	13.0	0.0	21.0	-5.13	6.34	0.73	-4.0	-21.0	5.0
Omalizumab 150mg	80	16.17	4.61	17.0	4.5	21.0	10.64	6.97	10.5	0.0	21.0	-5.52	6.29	0.70	-4.5	-21.0	7.0
Omalizumab 300mg	78	16.97	3.81	18.0	8.5	21.0	7.24	6.64	6.0	0.0	21.0	-9.73	6.79	0.77	-9.0	-21.0	2.0
Week 3																	
Placebo	77	16.69	4.41	18.0	5.0	21.0	12.74	5.95	14.0	0.0	21.0	-3.95	5.17	0.59	-2.0	-16.0	5.5
Omalizumab 75mg	73	17.08	4.24	19.0	7.5	21.0	11.89	6.60	12.0	0.0	21.0	-5.19	5.78	0.68	-4.0	-21.0	5.5
Omalizumab 150mg	79	16.16	4.64	17.0	4.5	21.0	10.14	7.11	10.0	0.0	21.0	-6.02	6.64	0.75	-5.0	-21.0	5.5
Omalizumab 300mg	78	16.97	3.81	18.0	8.5	21.0	6.94	6.97	4.5	0.0	21.0	-10.04	7.44	0.84	-9.3	-21.0	6.5
Week 4																	
Placebo	73	16.66	4.38	18.0	5.0	21.0	13.10	6.09	13.4	0.0	21.0	-3.56	5.11	0.60	-2.2	-16.0	10.0
Omalizumab 75mg	71	17.08	4.26	19.0	7.5	21.0	12.48	7.11	14.0	0.0	21.0	-4.61	6.17	0.73	-2.0	-21.0	5.0
Omalizumab 150mg	76	16.18	4.62	17.3	4.5	21.0	11.13	7.57	10.8	0.0	21.0	-5.06	6.95	0.80	-4.0	-21.0	10.5
Omalizumab 300mg	76	17.11	3.75	18.3	8.5	21.0	7.24	7.10	6.3	0.0	21.0	-9.87	7.46	0.86	-9.5	-21.0	5.5
Week 5																	
Placebo	69	16.55	4.44	18.0	5.0	21.0	11.64	6.97	14.0	0.0	21.0	-4.91	6.43	0.77	-3.0	-20.0	6.0
Omalizumab 75mg	65	17.15	4.23	19.0	7.5	21.0	10.30	6.95	9.5	0.0	21.0	-6.86	6.46	0.80	-4.5	-21.0	3.0
Omalizumab 150mg	69	16.03	4.60	17.0	4.5	21.0	9.12	7.32	8.0	0.0	21.0	-6.91	7.28	0.88	-6.0	-21.0	9.7
Omalizumab 300mg	74	16.95	3.87	18.0	8.5	21.0	5.96	6.77	2.8	0.0	21.0	-10.99	7.12	0.83	-10.5	-21.0	6.5

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 6																	
Placebo	70	16.51	4.38	17.8	5.0	21.0	11.20	7.03	13.0	0.0	21.0	-5.31	6.57	0.79	-3.5	-21.0	4.5
Omalizumab 75mg	72	17.03	4.25	19.0	7.5	21.0	9.44	6.87	8.8	0.0	21.0	-7.58	6.75	0.80	-6.9	-21.0	4.7
Omalizumab 150mg	75	16.17	4.63	17.0	4.5	21.0	8.79	7.49	7.5	0.0	21.0	-7.38	7.20	0.83	-7.0	-21.0	5.5
Omalizumab 300mg	75	16.99	3.86	18.0	8.5	21.0	5.38	6.47	3.5	0.0	21.0	-11.60	6.81	0.79	-12.0	-21.0	5.5
Week 7																	
Placebo	69	16.46	4.39	17.5	5.0	21.0	11.52	6.65	12.5	0.0	21.0	-4.94	6.50	0.78	-3.0	-20.5	6.0
Omalizumab 75mg	72	17.03	4.25	19.0	7.5	21.0	9.63	7.40	8.5	0.0	21.0	-7.40	6.84	0.81	-7.0	-21.0	5.5
Omalizumab 150mg	73	16.09	4.66	17.0	4.5	21.0	7.32	7.13	5.5	0.0	21.0	-8.77	7.00	0.82	-8.0	-21.0	3.5
Omalizumab 300mg	76	16.97	3.83	18.0	8.5	21.0	5.42	6.70	1.3	0.0	21.0	-11.55	7.18	0.82	-12.3	-21.0	5.0
Week 8																	
Placebo	67	16.37	4.42	17.5	5.0	21.0	11.67	6.85	12.3	0.0	21.0	-4.70	6.47	0.79	-3.0	-21.0	6.2
Omalizumab 75mg	68	17.12	4.15	19.0	7.5	21.0	10.59	7.42	10.1	0.0	21.0	-6.53	6.93	0.84	-5.5	-21.0	5.5
Omalizumab 150mg	69	16.16	4.66	17.5	4.5	21.0	7.55	7.37	5.5	0.0	21.0	-8.61	7.05	0.85	-8.0	-21.0	4.5
Omalizumab 300mg	73	17.10	3.76	18.0	8.5	21.0	5.26	6.60	2.0	0.0	20.5	-11.85	7.19	0.84	-12.5	-21.0	6.0
Week 9																	
Placebo	60	16.42	4.34	17.5	7.0	21.0	10.56	7.51	12.3	0.0	21.0	-5.86	7.08	0.91	-4.8	-20.5	6.5
Omalizumab 75mg	62	17.19	4.28	19.0	7.5	21.0	9.63	7.13	7.8	0.0	21.0	-7.57	7.10	0.90	-7.3	-21.0	3.5
Omalizumab 150mg	61	16.27	4.66	17.5	4.5	21.0	6.29	6.95	3.5	0.0	21.0	-9.98	6.73	0.86	-10.5	-21.0	2.0
Omalizumab 300mg	68	16.87	3.83	17.8	8.5	21.0	4.63	5.74	2.4	0.0	21.0	-12.24	6.08	0.74	-12.0	-21.0	3.0
Week 10																	
Placebo	64	16.51	4.24	17.5	7.0	21.0	11.20	6.90	12.0	0.0	21.0	-5.31	6.84	0.86	-4.3	-21.0	9.0
Omalizumab 75mg	68	17.10	4.20	19.0	7.5	21.0	8.77	7.08	7.3	0.0	21.0	-8.34	7.28	0.88	-7.5	-21.0	4.0
Omalizumab 150mg	67	15.93	4.73	17.0	4.5	21.0	5.71	6.31	3.5	0.0	21.0	-10.22	6.67	0.81	-10.0	-21.0	2.0
Omalizumab 300mg	74	16.93	3.86	18.0	8.5	21.0	4.41	6.29	1.0	0.0	20.5	-12.52	7.14	0.83	-13.8	-21.0	6.0
Week 11																	
Placebo	64	16.53	4.23	17.5	7.0	21.0	11.17	7.01	12.5	0.0	21.0	-5.36	6.84	0.86	-5.0	-21.0	8.4
Omalizumab 75mg	68	17.10	4.20	19.0	7.5	21.0	8.61	7.06	7.0	0.0	21.0	-8.49	7.15	0.87	-7.5	-21.0	5.0
Omalizumab 150mg	66	15.88	4.76	17.0	4.5	21.0	5.30	6.06	2.8	0.0	21.0	-10.58	6.73	0.83	-10.0	-21.0	1.0
Omalizumab 300mg	74	16.93	3.86	18.0	8.5	21.0	4.30	5.98	0.5	0.0	21.0	-12.63	6.89	0.80	-13.0	-21.0	6.0

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 12																	
Placebo	64	16.53	4.23	17.5	7.0	21.0	11.07	7.10	9.8	0.0	21.0	-5.46	6.97	0.87	-4.2	-21.0	7.3
Omalizumab 75mg	66	17.28	4.11	19.0	7.5	21.0	8.69	7.25	7.3	0.0	21.0	-8.59	7.44	0.92	-8.0	-21.0	5.5
Omalizumab 150mg	64	15.78	4.78	16.8	4.5	21.0	6.06	6.45	3.5	0.0	21.0	-9.73	6.61	0.83	-10.0	-21.0	2.1
Omalizumab 300mg	73	16.90	3.84	18.0	8.5	21.0	4.30	5.83	0.7	0.0	21.0	-12.60	6.52	0.76	-12.5	-21.0	3.0
Week 13																	
Placebo	50	16.03	4.48	17.0	7.0	21.0	9.54	6.56	9.0	0.0	21.0	-6.49	6.85	0.97	-5.3	-20.5	7.3
Omalizumab 75mg	61	17.29	4.16	19.0	7.5	21.0	7.82	7.38	6.4	0.0	21.0	-9.47	7.23	0.93	-9.8	-21.0	3.0
Omalizumab 150mg	57	16.36	4.54	17.5	4.5	21.0	5.51	6.28	3.5	0.0	21.0	-10.85	6.47	0.86	-12.0	-21.0	2.3
Omalizumab 300mg	68	16.90	3.90	18.0	8.5	21.0	4.04	6.01	0.6	0.0	21.0	-12.86	6.70	0.81	-12.8	-21.0	3.0
Week 14																	
Placebo	60	16.43	4.22	17.5	7.0	21.0	9.29	6.45	8.0	0.0	21.0	-7.15	7.08	0.91	-6.0	-21.0	11.5
Omalizumab 75mg	66	17.30	4.08	19.0	7.5	21.0	7.48	7.68	5.0	0.0	21.0	-9.83	7.66	0.94	-9.8	-21.0	3.0
Omalizumab 150mg	63	15.81	4.82	17.0	4.5	21.0	4.75	5.55	2.5	0.0	21.0	-11.06	6.33	0.80	-10.5	-21.0	0.5
Omalizumab 300mg	72	16.84	3.84	17.8	8.5	21.0	3.95	5.96	0.3	0.0	21.0	-12.89	6.71	0.79	-13.8	-21.0	2.0
Week 15																	
Placebo	59	16.55	4.15	17.5	7.0	21.0	9.15	6.67	7.5	0.0	21.0	-7.41	6.99	0.91	-7.0	-21.0	9.0
Omalizumab 75mg	65	17.27	4.11	19.0	7.5	21.0	7.99	7.72	5.5	0.0	21.0	-9.28	7.80	0.97	-8.5	-21.0	5.5
Omalizumab 150mg	63	15.81	4.82	17.0	4.5	21.0	5.18	5.90	4.0	0.0	21.0	-10.63	6.49	0.82	-10.0	-21.0	2.0
Omalizumab 300mg	71	16.85	3.87	18.0	8.5	21.0	4.16	6.60	0.0	0.0	21.0	-12.69	7.26	0.86	-14.5	-21.0	5.0
Week 16																	
Placebo	59	16.55	4.15	17.5	7.0	21.0	9.17	6.74	7.0	0.0	21.0	-7.38	6.77	0.88	-7.5	-21.0	5.0
Omalizumab 75mg	66	17.20	4.12	19.0	7.5	21.0	8.63	7.75	6.4	0.0	21.0	-8.57	7.69	0.95	-7.5	-21.0	5.5
Omalizumab 150mg	61	15.71	4.86	16.5	4.5	21.0	5.42	5.86	4.0	0.0	21.0	-10.29	6.22	0.80	-9.5	-21.0	1.5
Omalizumab 300mg	71	16.94	3.78	18.0	8.5	21.0	4.05	6.22	0.0	0.0	21.0	-12.88	6.85	0.81	-12.9	-21.0	3.0
Week 17																	
Placebo	55	16.59	4.24	17.5	7.0	21.0	8.02	6.60	7.0	0.0	21.0	-8.57	6.52	0.88	-8.0	-21.0	4.1
Omalizumab 75mg	59	17.11	4.12	19.0	7.5	21.0	7.47	7.47	6.1	0.0	21.0	-9.64	7.72	1.01	-9.5	-21.0	3.0
Omalizumab 150mg	57	15.89	4.89	17.0	4.5	21.0	4.91	6.17	2.3	0.0	21.0	-10.98	6.66	0.88	-10.7	-21.0	4.1
Omalizumab 300mg	65	16.76	3.92	18.0	8.5	21.0	2.99	5.06	0.0	0.0	21.0	-13.77	6.10	0.76	-15.4	-21.0	2.1

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 18																	
Placebo	57	16.41	4.22	17.5	7.0	21.0	8.67	6.70	7.5	0.0	21.0	-7.74	6.73	0.89	-7.0	-21.0	7.0
Omalizumab 75mg	64	17.33	4.07	19.0	7.5	21.0	6.87	7.59	4.1	0.0	21.0	-10.46	7.56	0.94	-10.5	-21.0	3.0
Omalizumab 150mg	62	15.75	4.83	16.8	4.5	21.0	4.63	5.01	3.0	0.0	15.5	-11.12	6.20	0.79	-10.8	-21.0	1.0
Omalizumab 300mg	71	16.85	3.87	18.0	8.5	21.0	2.98	5.10	0.0	0.0	21.0	-13.87	6.09	0.72	-15.0	-21.0	0.5
Week 19																	
Placebo	57	16.39	4.20	17.5	7.0	21.0	8.86	6.89	7.0	0.0	21.0	-7.52	6.87	0.91	-7.0	-20.5	7.5
Omalizumab 75mg	64	17.33	4.07	19.0	7.5	21.0	7.86	7.91	6.0	0.0	21.0	-9.47	7.86	0.98	-10.0	-21.0	3.5
Omalizumab 150mg	62	15.75	4.83	16.8	4.5	21.0	4.73	5.64	2.5	0.0	19.0	-11.02	6.22	0.79	-10.5	-21.0	1.0
Omalizumab 300mg	72	16.84	3.84	17.8	8.5	21.0	2.65	5.06	0.0	0.0	21.0	-14.19	6.10	0.72	-15.8	-21.0	4.0
Week 20																	
Placebo	55	16.38	4.25	17.5	7.0	21.0	8.18	6.97	7.0	0.0	21.0	-8.20	7.08	0.96	-8.5	-21.0	7.7
Omalizumab 75mg	61	17.20	4.12	19.0	7.5	21.0	8.31	7.95	7.0	0.0	21.0	-8.88	7.67	0.98	-8.0	-21.0	4.0
Omalizumab 150mg	61	15.68	4.84	16.5	4.5	21.0	4.74	5.40	2.8	0.0	20.5	-10.94	6.03	0.77	-11.2	-21.0	3.5
Omalizumab 300mg	68	16.92	3.85	18.0	8.5	21.0	2.55	5.00	0.0	0.0	21.0	-14.37	5.71	0.69	-15.0	-21.0	0.0
Week 21																	
Placebo	50	16.74	4.01	17.8	7.5	21.0	7.39	6.94	4.8	0.0	21.0	-9.35	7.01	0.99	-9.1	-21.0	7.0
Omalizumab 75mg	59	17.36	4.10	19.0	7.5	21.0	8.05	7.48	6.5	0.0	21.0	-9.31	7.25	0.94	-10.0	-21.0	3.0
Omalizumab 150mg	52	16.38	4.46	17.5	7.0	21.0	5.03	5.52	3.3	0.0	18.9	-11.34	5.94	0.82	-12.1	-21.0	3.5
Omalizumab 300mg	67	16.93	3.77	17.5	8.5	21.0	2.32	4.26	0.0	0.0	21.0	-14.62	5.40	0.66	-16.0	-21.0	0.0
Week 22																	
Placebo	55	16.43	4.22	17.5	7.0	21.0	7.36	6.70	6.5	0.0	21.0	-9.07	6.96	0.94	-9.0	-21.0	7.0
Omalizumab 75mg	64	17.35	4.08	19.0	7.5	21.0	6.77	7.19	5.3	0.0	21.0	-10.58	7.33	0.92	-10.5	-21.0	3.0
Omalizumab 150mg	58	15.91	4.80	17.3	4.5	21.0	5.59	6.84	2.3	0.0	21.0	-10.32	6.90	0.91	-10.8	-21.0	3.5
Omalizumab 300mg	70	16.91	3.80	17.8	8.5	21.0	2.21	4.46	0.0	0.0	21.0	-14.70	5.58	0.67	-16.0	-21.0	0.0
Week 23																	
Placebo	56	16.50	4.22	17.5	7.0	21.0	7.87	6.97	7.0	0.0	21.0	-8.63	7.28	0.97	-8.4	-21.0	9.5
Omalizumab 75mg	63	17.40	4.09	19.0	7.5	21.0	7.38	7.55	6.0	0.0	21.0	-10.03	7.56	0.95	-10.3	-21.0	3.0
Omalizumab 150mg	58	15.72	4.81	16.8	4.5	21.0	4.79	5.95	1.5	0.0	20.5	-10.94	6.63	0.87	-11.4	-21.0	3.5
Omalizumab 300mg	71	16.81	3.86	17.5	8.5	21.0	2.12	4.42	0.0	0.0	21.0	-14.69	5.57	0.66	-16.0	-21.0	0.0

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 24																	
Placebo	55	16.43	4.22	17.5	7.0	21.0	7.23	6.93	5.5	0.0	21.0	-9.20	7.05	0.95	-10.0	-21.0	7.0
Omalizumab 75mg	63	17.40	4.09	19.0	7.5	21.0	7.69	7.65	6.5	0.0	21.0	-9.71	7.46	0.94	-9.0	-21.0	3.0
Omalizumab 150mg	57	15.72	4.85	17.0	4.5	21.0	4.85	6.16	2.0	0.0	21.0	-10.87	6.31	0.84	-10.5	-21.0	2.5
Omalizumab 300mg	70	16.76	3.86	17.5	8.5	21.0	2.55	5.02	0.0	0.0	21.0	-14.21	5.87	0.70	-15.3	-21.0	0.5
Week 25																	
Placebo	52	16.33	4.28	17.3	7.0	21.0	7.40	6.45	6.7	0.0	21.0	-8.93	7.03	0.98	-8.5	-21.0	6.5
Omalizumab 75mg	60	17.28	4.14	19.0	7.5	21.0	8.46	7.43	6.8	0.0	21.0	-8.82	7.21	0.93	-8.0	-21.0	3.0
Omalizumab 150mg	57	15.82	4.79	17.0	4.5	21.0	6.24	6.58	4.5	0.0	21.0	-9.58	6.26	0.83	-9.5	-21.0	1.5
Omalizumab 300mg	69	16.86	3.80	17.5	8.5	21.0	2.89	5.41	0.0	0.0	21.0	-13.97	5.91	0.71	-15.5	-21.0	1.5
Week 26																	
Placebo	48	16.39	4.28	17.3	7.0	21.0	7.24	6.60	6.5	0.0	21.0	-9.15	7.28	1.05	-10.3	-21.0	8.0
Omalizumab 75mg	60	17.43	4.07	19.0	7.5	21.0	9.98	7.70	8.8	0.0	21.0	-7.44	7.60	0.98	-5.5	-21.0	3.0
Omalizumab 150mg	53	15.89	4.68	17.0	4.5	21.0	7.60	6.81	7.0	0.0	21.0	-8.29	6.46	0.89	-7.6	-21.0	3.5
Omalizumab 300mg	70	16.73	3.84	17.5	8.5	21.0	3.72	5.62	1.3	0.0	21.0	-13.01	6.35	0.76	-14.3	-21.0	4.0
Week 27																	
Placebo	49	16.43	4.24	17.5	7.0	21.0	7.79	6.69	7.0	0.0	21.0	-8.64	7.47	1.07	-8.0	-21.0	9.0
Omalizumab 75mg	59	17.40	4.10	19.0	7.5	21.0	10.40	7.67	9.5	0.0	21.0	-7.00	7.22	0.94	-6.5	-21.0	3.5
Omalizumab 150mg	52	15.86	4.72	16.8	4.5	21.0	7.77	6.91	7.0	0.0	21.0	-8.09	6.23	0.86	-7.7	-21.0	1.0
Omalizumab 300mg	67	16.96	3.69	18.0	9.0	21.0	4.43	5.82	1.5	0.0	21.0	-12.54	6.20	0.76	-12.5	-21.0	0.0
Week 28																	
Placebo	49	16.42	4.23	17.5	7.0	21.0	6.95	6.09	6.5	0.0	21.0	-9.47	7.08	1.01	-9.0	-21.0	5.5
Omalizumab 75mg	56	17.38	4.14	19.0	7.5	21.0	10.74	7.56	10.5	0.0	21.0	-6.63	7.31	0.98	-4.5	-21.0	4.5
Omalizumab 150mg	51	15.91	4.75	17.0	4.5	21.0	8.35	6.91	7.5	0.0	21.0	-7.56	6.12	0.86	-7.0	-21.0	1.0
Omalizumab 300mg	67	16.81	3.76	17.5	9.0	21.0	5.37	6.62	2.0	0.0	21.0	-11.43	6.85	0.84	-12.0	-21.0	3.0
Week 29																	
Placebo	47	16.32	4.28	17.5	7.0	21.0	6.77	6.13	7.0	0.0	21.0	-9.55	7.27	1.06	-9.0	-21.0	6.0
Omalizumab 75mg	56	17.40	4.05	19.0	7.5	21.0	11.02	7.59	11.8	0.0	21.0	-6.39	7.11	0.95	-4.8	-21.0	4.5
Omalizumab 150mg	51	15.93	4.77	17.0	4.5	21.0	8.83	7.42	7.0	0.0	21.0	-7.10	7.29	1.02	-6.5	-21.0	5.4
Omalizumab 300mg	64	16.77	3.69	17.5	9.0	21.0	6.10	6.41	5.3	0.0	21.0	-10.68	6.73	0.84	-10.5	-21.0	5.0

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 30																	
Placebo	46	16.24	4.29	17.3	7.0	21.0	6.52	6.21	6.8	0.0	21.0	-9.72	7.07	1.04	-8.0	-21.0	5.0
Omalizumab 75mg	54	17.38	4.09	19.0	7.5	21.0	10.33	7.22	10.0	0.0	21.0	-7.05	7.21	0.98	-5.3	-21.0	5.0
Omalizumab 150mg	51	15.93	4.77	17.0	4.5	21.0	8.47	7.58	8.0	0.0	21.0	-7.46	7.44	1.04	-7.0	-21.0	5.5
Omalizumab 300mg	62	16.74	3.74	17.5	9.0	21.0	7.60	7.26	6.8	0.0	21.0	-9.14	7.59	0.96	-9.1	-21.0	6.5
Week 31																	
Placebo	45	16.19	4.32	17.0	7.0	21.0	7.15	6.83	6.0	0.0	21.0	-9.04	7.63	1.14	-9.5	-21.0	10.0
Omalizumab 75mg	52	17.27	4.12	19.0	7.5	21.0	10.92	7.42	10.0	0.0	21.0	-6.35	7.07	0.98	-5.0	-21.0	4.5
Omalizumab 150mg	51	15.93	4.77	17.0	4.5	21.0	8.53	6.70	7.0	0.0	21.0	-7.40	6.49	0.91	-7.0	-20.5	4.0
Omalizumab 300mg	60	16.65	3.75	17.3	9.0	21.0	7.66	7.55	5.5	0.0	21.0	-8.99	7.87	1.02	-10.5	-21.0	6.0
Week 32																	
Placebo	45	16.19	4.32	17.0	7.0	21.0	7.54	7.02	5.5	0.0	21.0	-8.65	7.68	1.15	-9.0	-21.0	7.5
Omalizumab 75mg	51	17.20	4.13	19.0	7.5	21.0	10.56	7.29	11.0	0.0	21.0	-6.63	6.93	0.97	-5.0	-21.0	4.0
Omalizumab 150mg	50	15.90	4.81	16.8	4.5	21.0	8.44	7.15	7.0	0.0	21.0	-7.46	7.52	1.06	-7.5	-21.0	6.5
Omalizumab 300mg	58	16.62	3.80	17.3	9.0	21.0	8.16	7.86	6.8	0.0	21.0	-8.46	8.09	1.06	-8.8	-21.0	8.5
Week 33																	
Placebo	45	16.19	4.32	17.0	7.0	21.0	6.86	6.89	3.5	0.0	19.8	-9.33	7.85	1.17	-9.3	-21.0	8.0
Omalizumab 75mg	50	17.15	4.16	19.0	7.5	21.0	10.56	7.13	10.5	0.0	21.0	-6.59	6.52	0.92	-6.8	-21.0	3.5
Omalizumab 150mg	50	15.90	4.81	16.8	4.5	21.0	8.97	7.37	7.8	0.0	21.0	-6.93	7.28	1.03	-7.0	-21.0	8.0
Omalizumab 300mg	56	16.47	3.78	17.0	9.0	21.0	8.35	7.78	7.0	0.0	21.0	-8.12	8.36	1.12	-9.3	-21.0	6.5
Week 34																	
Placebo	47	16.33	4.29	17.5	7.0	21.0	7.03	7.20	3.5	0.0	21.0	-9.30	7.92	1.16	-8.5	-21.0	11.0
Omalizumab 75mg	49	17.08	4.17	19.0	7.5	21.0	10.70	7.41	11.0	0.0	21.0	-6.38	6.87	0.98	-4.5	-21.0	3.5
Omalizumab 150mg	50	15.90	4.81	16.8	4.5	21.0	9.09	7.18	7.8	0.0	21.0	-6.81	7.09	1.00	-6.0	-21.0	7.5
Omalizumab 300mg	54	16.54	3.80	17.0	9.0	21.0	8.72	7.86	7.0	0.0	21.0	-7.82	8.48	1.15	-7.3	-21.0	7.5
Week 35																	
Placebo	45	16.13	4.28	17.0	7.0	21.0	7.55	7.52	5.5	0.0	21.0	-8.58	8.27	1.23	-8.5	-21.0	12.0
Omalizumab 75mg	48	17.20	4.14	19.0	7.5	21.0	10.97	7.22	11.3	0.0	21.0	-6.23	6.77	0.98	-4.5	-21.0	3.0
Omalizumab 150mg	51	15.93	4.77	17.0	4.5	21.0	9.19	7.33	7.6	0.0	21.0	-6.75	7.04	0.99	-7.0	-21.0	8.0
Omalizumab 300mg	56	16.47	3.78	17.0	9.0	21.0	9.43	7.57	9.3	0.0	21.0	-7.04	8.20	1.10	-6.0	-21.0	8.5

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/7.2
Mean and Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 36																	
Placebo	46	16.52	4.13	17.5	7.0	21.0	7.01	7.14	5.5	0.0	21.0	-9.52	7.84	1.16	-8.3	-21.0	13.5
Omalizumab 75mg	48	17.20	4.14	19.0	7.5	21.0	10.63	7.04	10.8	0.0	21.0	-6.57	6.74	0.97	-5.5	-21.0	3.0
Omalizumab 150mg	51	15.93	4.77	17.0	4.5	21.0	8.95	7.40	7.0	0.0	21.0	-6.98	7.51	1.05	-7.0	-21.0	7.0
Omalizumab 300mg	56	16.47	3.78	17.0	9.0	21.0	8.90	7.91	7.8	0.0	21.0	-7.57	8.47	1.13	-6.5	-21.0	8.5
Week 37																	
Placebo	45	16.53	4.17	17.5	7.0	21.0	7.17	6.98	7.0	0.0	21.0	-9.36	7.64	1.14	-8.5	-21.0	14.0
Omalizumab 75mg	50	17.13	4.14	19.0	7.5	21.0	10.83	7.07	9.8	0.0	21.0	-6.30	6.40	0.91	-5.0	-21.0	3.0
Omalizumab 150mg	50	15.97	4.81	17.3	4.5	21.0	8.71	7.49	7.8	0.0	21.0	-7.26	7.45	1.05	-7.3	-21.0	6.0
Omalizumab 300mg	51	16.51	3.74	17.0	9.0	21.0	9.46	8.07	8.5	0.0	21.0	-7.05	8.72	1.22	-5.0	-21.0	8.0
Week 38																	
Placebo	44	16.49	4.21	17.5	7.0	21.0	6.49	6.76	4.8	0.0	21.0	-10.00	7.72	1.16	-9.5	-21.0	14.0
Omalizumab 75mg	48	17.23	4.13	19.0	7.5	21.0	10.10	7.44	8.8	0.0	21.0	-7.13	7.07	1.02	-5.0	-21.0	3.0
Omalizumab 150mg	50	15.97	4.81	17.3	4.5	21.0	8.61	7.72	7.0	0.0	21.0	-7.36	7.55	1.07	-6.5	-21.0	7.0
Omalizumab 300mg	52	16.53	3.71	17.0	9.0	21.0	9.49	7.89	9.3	0.0	21.0	-7.04	8.50	1.18	-5.0	-21.0	8.0
Week 39																	
Placebo	45	16.53	4.17	17.5	7.0	21.0	7.21	7.02	5.5	0.0	21.0	-9.33	7.59	1.13	-8.5	-21.0	12.0
Omalizumab 75mg	47	16.98	4.23	18.5	7.5	21.0	9.78	7.23	8.0	0.0	21.0	-7.20	6.91	1.01	-5.0	-21.0	3.0
Omalizumab 150mg	49	15.87	4.80	17.0	4.5	21.0	8.81	7.61	7.0	0.0	21.0	-7.05	7.76	1.11	-7.5	-21.0	9.3
Omalizumab 300mg	50	16.55	3.72	17.0	9.0	21.0	8.96	7.74	8.3	0.0	21.0	-7.59	8.45	1.19	-6.8	-21.0	9.5
Week 40																	
Placebo	41	16.80	3.83	17.5	8.0	21.0	6.82	6.66	5.0	0.0	21.0	-9.98	7.22	1.13	-9.0	-21.0	6.0
Omalizumab 75mg	46	16.89	4.23	18.5	7.5	21.0	9.67	7.27	8.8	0.0	21.0	-7.22	6.81	1.00	-6.0	-21.0	2.0
Omalizumab 150mg	49	15.88	4.81	17.0	4.5	21.0	8.67	7.54	7.0	0.0	21.0	-7.21	7.61	1.09	-7.0	-21.0	10.0
Omalizumab 300mg	47	16.54	3.74	17.0	9.0	21.0	9.24	7.85	8.5	0.0	21.0	-7.30	8.46	1.23	-6.5	-21.0	9.0

* Number of subjects with both baseline and visit values.
Baseline weekly number of hives score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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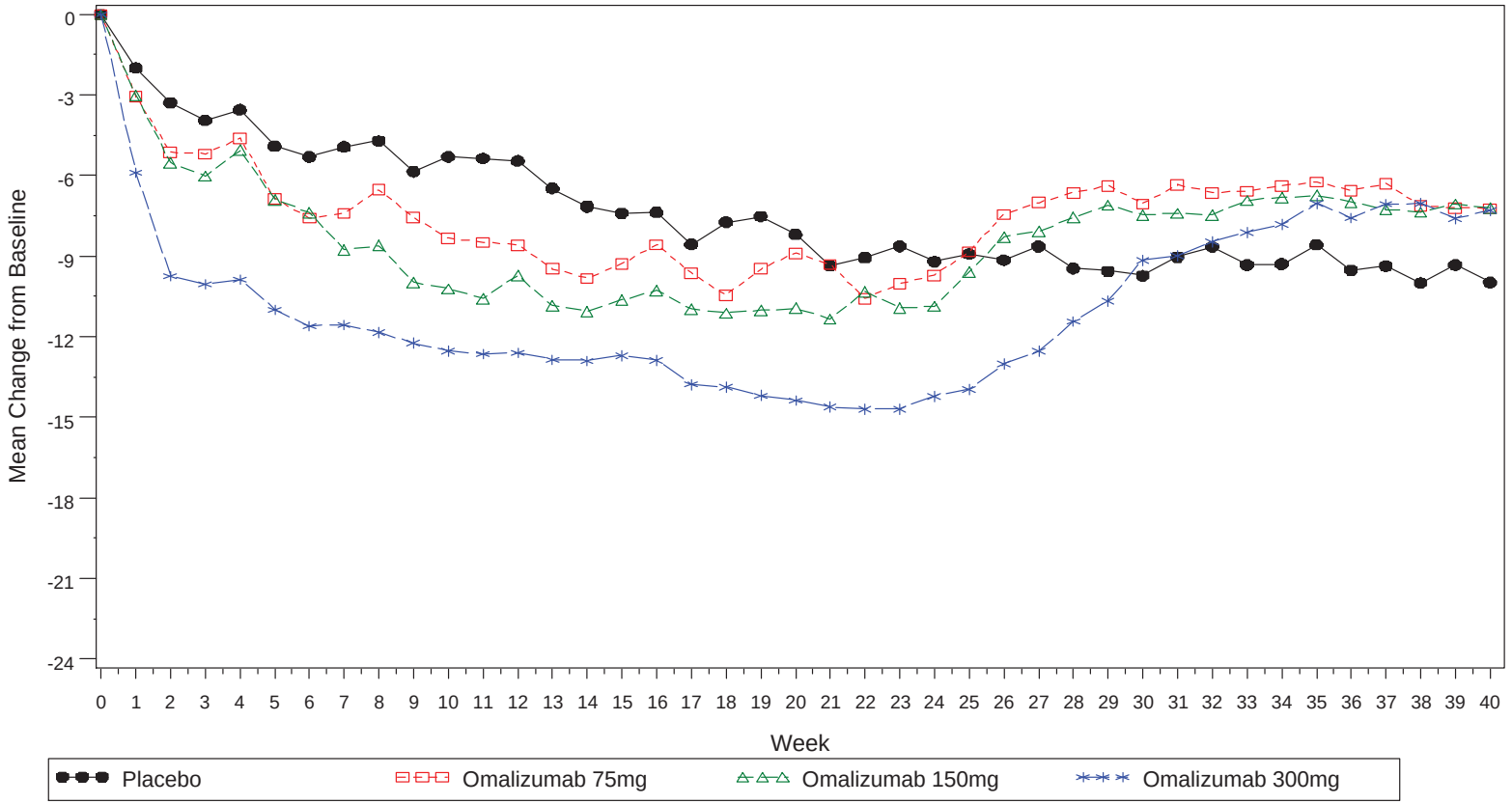
Figure 14.2/3.3
Mean Change from Baseline in Weekly Number of Hives Score by Study Week (Observed Data)
Modified Intention to Treat Patients



Number of Patients

Placebo	80	73	67	64	59	55	55	49	45	46	41
Omalizumab 75mg	77	71	68	66	66	61	63	56	51	48	46
Omalizumab 150mg	80	76	69	64	61	61	57	51	50	51	49
Omalizumab 300mg	81	76	73	73	71	68	70	67	58	56	47

Missing weekly scores are not imputed.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/g_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Baseline																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	15.64	4.22	16.0	6.0	21.0						
Omalizumab 75mg	77	15.54	4.38	15.5	4.0	21.0	15.54	4.38	15.5	4.0	21.0						
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	15.30	4.24	15.0	6.0	21.0						
Omalizumab 300mg	81	15.26	4.02	16.0	7.0	21.0	15.26	4.02	16.0	7.0	21.0						
Week 1																	
Placebo	80	15.64	4.22	16.0	6.0	21.0	13.93	4.61	14.0	4.0	21.0	-1.71	3.23	0.36	-1.5	-9.5	6.0
Omalizumab 75mg	76	15.64	4.31	15.5	4.0	21.0	13.11	4.82	13.0	1.0	21.0	-2.54	3.46	0.40	-1.8	-11.0	6.0
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	12.21	5.14	12.3	0.0	21.0	-3.09	4.71	0.53	-1.5	-18.0	4.5
Omalizumab 300mg	80	15.26	4.04	16.0	7.0	21.0	10.96	5.52	9.8	2.0	21.0	-4.30	4.77	0.53	-3.0	-15.0	4.0
Week 2																	
Placebo	77	15.48	4.22	16.0	6.0	21.0	12.65	5.53	13.0	0.0	21.0	-2.83	4.81	0.55	-2.0	-19.0	6.5
Omalizumab 75mg	75	15.59	4.32	15.5	4.0	21.0	11.10	6.48	11.0	0.0	21.0	-4.49	5.85	0.68	-3.0	-21.0	6.5
Omalizumab 150mg	80	15.30	4.24	15.0	6.0	21.0	10.31	6.10	11.0	0.0	21.0	-4.99	6.19	0.69	-2.5	-21.0	7.5
Omalizumab 300mg	78	15.14	4.02	16.0	7.0	21.0	7.57	6.28	7.3	0.0	21.0	-7.57	6.22	0.70	-7.0	-21.0	5.5
Week 3																	
Placebo	77	15.48	4.22	16.0	6.0	21.0	11.77	5.29	11.5	0.0	21.0	-3.71	4.96	0.57	-2.5	-19.0	6.5
Omalizumab 75mg	73	15.51	4.33	15.0	4.0	21.0	11.57	6.10	12.0	0.0	21.0	-3.94	5.25	0.61	-3.0	-21.0	4.5
Omalizumab 150mg	79	15.35	4.25	15.0	6.0	21.0	9.88	6.54	8.5	0.0	21.0	-5.47	6.42	0.72	-4.0	-21.0	7.5
Omalizumab 300mg	78	15.14	4.02	16.0	7.0	21.0	7.17	6.24	7.0	0.0	21.0	-7.97	6.34	0.72	-7.5	-21.0	5.5
Week 4																	
Placebo	73	15.38	4.25	16.0	6.0	21.0	11.72	5.32	11.5	0.0	21.0	-3.65	4.39	0.51	-2.5	-19.0	5.0
Omalizumab 75mg	71	15.40	4.33	15.0	4.0	21.0	11.65	6.18	11.5	0.0	21.0	-3.75	5.52	0.66	-2.5	-21.0	8.5
Omalizumab 150mg	76	15.35	4.31	15.0	6.0	21.0	10.64	6.42	11.0	0.0	21.0	-4.70	6.06	0.69	-3.7	-21.0	7.5
Omalizumab 300mg	76	15.14	4.07	16.0	7.0	21.0	7.69	6.59	7.0	0.0	21.0	-7.46	6.25	0.72	-6.5	-21.0	5.0
Week 5																	
Placebo	69	15.30	4.29	15.5	6.0	21.0	10.49	5.75	10.0	0.0	21.0	-4.80	5.57	0.67	-3.5	-19.0	4.5
Omalizumab 75mg	65	15.41	4.41	15.0	4.0	21.0	9.79	6.13	9.0	0.0	21.0	-5.62	5.94	0.74	-5.0	-21.0	5.5
Omalizumab 150mg	69	15.20	4.36	15.0	6.0	21.0	9.32	6.45	8.5	0.0	21.0	-5.88	6.77	0.81	-4.0	-21.0	9.8
Omalizumab 300mg	74	15.03	4.07	15.8	7.0	21.0	6.27	6.41	5.5	0.0	21.0	-8.75	6.35	0.74	-9.0	-21.0	2.5

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 6																	
Placebo	70	15.24	4.27	15.3	6.0	21.0	10.11	6.16	9.0	0.0	21.0	-5.12	5.87	0.70	-4.0	-21.0	3.0
Omalizumab 75mg	72	15.43	4.31	15.0	4.0	21.0	9.40	6.12	8.3	0.0	21.0	-6.03	5.85	0.69	-5.3	-21.0	6.5
Omalizumab 150mg	75	15.34	4.25	15.0	6.0	21.0	8.71	6.98	8.0	0.0	21.0	-6.63	7.24	0.84	-6.0	-21.0	7.5
Omalizumab 300mg	75	15.10	4.09	16.0	7.0	21.0	5.59	5.93	5.5	0.0	21.0	-9.51	6.42	0.74	-10.0	-21.0	3.5
Week 7																	
Placebo	69	15.17	4.26	15.0	6.0	21.0	10.62	5.89	10.5	0.0	21.0	-4.55	5.55	0.67	-3.5	-20.0	3.0
Omalizumab 75mg	72	15.43	4.31	15.0	4.0	21.0	9.36	6.55	8.3	0.0	21.0	-6.07	5.94	0.70	-5.8	-21.0	6.0
Omalizumab 150mg	73	15.34	4.29	15.0	6.0	21.0	7.61	6.68	7.0	0.0	21.0	-7.72	7.10	0.83	-7.0	-21.0	6.0
Omalizumab 300mg	76	15.13	4.07	16.0	7.0	21.0	5.11	6.03	2.7	0.0	21.0	-10.02	6.45	0.74	-10.0	-21.0	3.0
Week 8																	
Placebo	67	15.01	4.22	15.0	6.0	21.0	10.41	5.58	10.5	0.0	21.0	-4.59	5.39	0.66	-3.5	-21.0	4.5
Omalizumab 75mg	68	15.43	4.17	15.0	4.0	21.0	9.92	6.41	8.5	0.0	21.0	-5.50	5.87	0.71	-4.8	-21.0	6.5
Omalizumab 150mg	69	15.34	4.37	15.0	6.0	21.0	7.73	7.07	7.0	0.0	21.0	-7.62	7.28	0.88	-8.0	-21.0	9.0
Omalizumab 300mg	73	15.05	4.12	16.0	7.0	21.0	5.36	6.14	3.0	0.0	21.0	-9.69	6.55	0.77	-9.5	-21.0	3.3
Week 9																	
Placebo	60	15.07	4.44	15.0	6.0	21.0	9.40	6.13	8.9	0.0	21.0	-5.67	6.02	0.78	-3.8	-21.0	3.0
Omalizumab 75mg	62	15.50	4.45	15.5	4.0	21.0	9.18	6.04	8.8	0.0	21.0	-6.32	6.20	0.79	-5.0	-21.0	6.5
Omalizumab 150mg	61	15.77	4.19	16.0	6.0	21.0	6.38	6.48	4.5	0.0	21.0	-9.39	6.80	0.87	-10.0	-21.0	1.8
Omalizumab 300mg	68	15.13	4.23	16.0	7.0	21.0	4.79	5.63	2.1	0.0	21.0	-10.34	6.50	0.79	-9.6	-21.0	1.5
Week 10																	
Placebo	64	15.22	4.22	15.0	6.0	21.0	10.13	5.91	10.0	0.0	21.0	-5.09	5.86	0.73	-3.8	-21.0	4.5
Omalizumab 75mg	68	15.54	4.37	15.3	4.0	21.0	8.86	6.37	7.8	0.0	21.0	-6.69	6.50	0.79	-6.5	-21.0	6.5
Omalizumab 150mg	67	15.38	4.42	15.0	6.0	21.0	6.17	6.34	4.5	0.0	21.0	-9.22	6.98	0.85	-10.5	-21.0	6.5
Omalizumab 300mg	74	15.09	4.12	15.8	7.0	21.0	4.41	5.95	1.5	0.0	21.0	-10.68	6.65	0.77	-11.0	-21.0	2.0
Week 11																	
Placebo	64	15.10	4.34	15.0	6.0	21.0	10.16	6.09	9.5	0.0	21.0	-4.94	5.75	0.72	-4.3	-21.0	5.5
Omalizumab 75mg	68	15.54	4.37	15.3	4.0	21.0	8.70	6.31	7.8	0.0	21.0	-6.85	6.05	0.73	-6.0	-21.0	4.5
Omalizumab 150mg	66	15.33	4.43	15.0	6.0	21.0	5.99	6.22	4.6	0.0	21.0	-9.33	6.89	0.85	-10.0	-21.0	5.5
Omalizumab 300mg	74	15.09	4.12	15.8	7.0	21.0	4.43	5.76	1.0	0.0	21.0	-10.67	6.62	0.77	-11.0	-21.0	2.0

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 12																	
Placebo	64	15.10	4.34	15.0	6.0	21.0	10.18	6.11	10.0	0.0	21.0	-4.92	5.68	0.71	-3.8	-21.0	4.0
Omalizumab 75mg	66	15.59	4.42	15.5	4.0	21.0	8.35	6.60	7.0	0.0	21.0	-7.24	6.22	0.77	-6.5	-21.0	2.0
Omalizumab 150mg	64	15.32	4.39	15.0	6.0	21.0	6.62	6.40	6.0	0.0	21.0	-8.71	6.36	0.80	-8.3	-21.0	2.5
Omalizumab 300mg	73	15.20	4.10	16.0	7.0	21.0	4.34	5.41	1.4	0.0	21.0	-10.86	6.12	0.72	-11.0	-21.0	3.0
Week 13																	
Placebo	50	14.79	4.42	14.5	6.0	21.0	8.59	5.26	7.8	0.0	21.0	-6.20	5.94	0.84	-5.0	-21.0	3.7
Omalizumab 75mg	61	15.56	4.49	15.5	4.0	21.0	7.79	6.77	7.0	0.0	21.0	-7.76	6.49	0.83	-7.0	-21.0	5.0
Omalizumab 150mg	57	15.69	4.20	15.0	6.0	21.0	6.38	6.50	5.0	0.0	21.0	-9.31	6.15	0.81	-10.0	-19.5	1.8
Omalizumab 300mg	68	15.27	4.13	16.0	7.0	21.0	4.24	5.88	1.1	0.0	21.0	-11.03	6.49	0.79	-11.5	-21.0	2.0
Week 14																	
Placebo	60	15.30	4.45	15.8	6.0	21.0	9.43	6.02	9.3	0.0	21.0	-5.87	6.13	0.79	-5.0	-21.0	8.5
Omalizumab 75mg	66	15.58	4.43	15.5	4.0	21.0	7.21	6.90	7.0	0.0	21.0	-8.36	6.89	0.85	-7.8	-21.0	3.5
Omalizumab 150mg	63	15.40	4.38	15.0	6.0	21.0	5.46	5.67	3.5	0.0	21.0	-9.94	6.68	0.84	-10.5	-21.0	3.0
Omalizumab 300mg	72	15.25	4.11	16.0	7.0	21.0	4.28	5.99	0.5	0.0	21.0	-10.97	6.47	0.76	-11.3	-21.0	3.0
Week 15																	
Placebo	59	15.35	4.47	16.0	6.0	21.0	8.99	5.91	8.0	0.0	21.0	-6.36	6.03	0.79	-5.0	-21.0	2.5
Omalizumab 75mg	65	15.55	4.46	15.5	4.0	21.0	7.82	7.09	7.0	0.0	21.0	-7.73	7.06	0.88	-7.5	-21.0	6.0
Omalizumab 150mg	63	15.40	4.38	15.0	6.0	21.0	6.07	6.38	6.0	0.0	21.0	-9.32	6.98	0.88	-10.0	-21.0	3.5
Omalizumab 300mg	71	15.23	4.13	16.0	7.0	21.0	4.30	6.13	0.0	0.0	21.0	-10.93	6.80	0.81	-11.5	-21.0	5.0
Week 16																	
Placebo	59	15.35	4.47	16.0	6.0	21.0	8.94	5.82	7.6	0.0	21.0	-6.40	5.95	0.77	-6.0	-21.0	5.0
Omalizumab 75mg	66	15.54	4.42	15.3	4.0	21.0	8.85	7.38	7.0	0.0	21.0	-6.69	7.42	0.91	-6.3	-21.0	11.5
Omalizumab 150mg	61	15.34	4.42	15.0	6.0	21.0	6.35	6.48	6.0	0.0	21.0	-8.99	6.57	0.84	-9.3	-21.0	1.0
Omalizumab 300mg	71	15.27	4.13	16.0	7.0	21.0	4.29	6.08	0.0	0.0	21.0	-10.98	6.72	0.80	-11.5	-21.0	5.5
Week 17																	
Placebo	55	15.25	4.51	15.5	6.0	21.0	8.13	5.93	7.7	0.0	21.0	-7.12	5.96	0.80	-5.7	-21.0	3.5
Omalizumab 75mg	59	15.69	4.29	15.0	4.0	21.0	7.35	6.99	5.3	0.0	21.0	-8.33	7.23	0.94	-7.5	-21.0	7.0
Omalizumab 150mg	57	15.52	4.20	15.0	6.0	21.0	5.54	6.32	4.0	0.0	21.0	-9.97	6.26	0.83	-11.0	-21.0	3.6
Omalizumab 300mg	65	15.05	4.13	15.5	7.0	21.0	3.37	5.56	0.0	0.0	21.0	-11.68	6.23	0.77	-12.0	-21.0	6.0

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 18																	
Placebo	57	15.22	4.45	15.5	6.0	21.0	8.32	5.57	7.5	0.0	21.0	-6.90	5.99	0.79	-5.5	-21.0	3.5
Omalizumab 75mg	64	15.66	4.30	15.5	4.0	21.0	6.72	7.06	4.3	0.0	21.0	-8.93	7.31	0.91	-9.5	-21.0	5.5
Omalizumab 150mg	62	15.24	4.35	15.0	6.0	21.0	5.63	5.94	5.4	0.0	21.0	-9.61	6.61	0.84	-9.8	-21.0	3.8
Omalizumab 300mg	71	15.23	4.13	16.0	7.0	21.0	3.25	5.16	0.0	0.0	21.0	-11.98	6.16	0.73	-13.0	-21.0	4.5
Week 19																	
Placebo	57	15.18	4.41	15.5	6.0	21.0	8.89	6.15	7.5	0.0	21.0	-6.30	6.39	0.85	-6.0	-19.0	7.8
Omalizumab 75mg	64	15.66	4.30	15.5	4.0	21.0	7.76	7.29	7.0	0.0	21.0	-7.89	7.71	0.96	-7.0	-21.0	6.0
Omalizumab 150mg	62	15.24	4.35	15.0	6.0	21.0	5.20	5.65	4.0	0.0	21.0	-10.04	6.56	0.83	-10.3	-21.0	3.0
Omalizumab 300mg	72	15.25	4.11	16.0	7.0	21.0	2.90	5.05	0.0	0.0	21.0	-12.35	5.99	0.71	-13.5	-21.0	2.0
Week 20																	
Placebo	55	15.23	4.47	16.0	6.0	21.0	8.30	5.87	7.5	0.0	21.0	-6.93	6.18	0.83	-6.0	-21.0	4.0
Omalizumab 75mg	61	15.50	4.33	15.0	4.0	21.0	8.29	7.35	7.0	0.0	21.0	-7.21	7.28	0.93	-6.8	-21.0	6.5
Omalizumab 150mg	61	15.17	4.35	15.0	6.0	21.0	5.63	5.67	5.0	0.0	21.0	-9.54	6.17	0.79	-9.5	-21.0	3.0
Omalizumab 300mg	68	15.31	4.20	16.0	7.0	21.0	3.03	5.14	0.0	0.0	21.0	-12.28	6.08	0.74	-12.5	-21.0	4.5
Week 21																	
Placebo	50	15.49	4.40	15.8	6.0	21.0	7.44	5.92	6.8	0.0	21.0	-8.05	6.16	0.87	-7.3	-21.0	2.0
Omalizumab 75mg	59	15.89	4.23	15.5	4.0	21.0	7.86	6.71	7.0	0.0	21.0	-8.03	6.92	0.90	-7.5	-21.0	5.5
Omalizumab 150mg	52	15.47	4.26	15.0	6.0	21.0	6.02	5.91	4.3	0.0	19.6	-9.45	6.41	0.89	-10.0	-21.0	3.6
Omalizumab 300mg	67	15.42	4.02	16.0	7.0	21.0	2.65	4.58	0.0	0.0	21.0	-12.77	6.00	0.73	-13.0	-21.0	5.0
Week 22																	
Placebo	55	15.17	4.45	15.5	6.0	21.0	7.37	5.83	7.0	0.0	21.0	-7.80	6.40	0.86	-7.0	-21.0	4.5
Omalizumab 75mg	64	15.69	4.32	15.5	4.0	21.0	6.83	6.71	6.0	0.0	21.0	-8.85	7.00	0.87	-8.2	-21.0	5.5
Omalizumab 150mg	58	15.31	4.28	15.0	6.0	21.0	5.85	6.37	5.5	0.0	21.0	-9.46	6.61	0.87	-10.3	-21.0	3.0
Omalizumab 300mg	70	15.31	4.15	16.0	7.0	21.0	2.57	4.90	0.0	0.0	21.0	-12.74	5.98	0.72	-14.3	-21.0	4.0
Week 23																	
Placebo	56	15.28	4.48	15.8	6.0	21.0	7.87	6.25	7.0	0.0	21.0	-7.40	6.67	0.89	-7.3	-21.0	7.0
Omalizumab 75mg	63	15.81	4.24	15.5	4.0	21.0	7.91	7.35	7.0	0.0	21.0	-7.90	7.33	0.92	-7.0	-21.0	6.5
Omalizumab 150mg	58	15.22	4.21	15.0	6.0	21.0	5.67	6.13	3.3	0.0	21.0	-9.55	6.62	0.87	-9.8	-21.0	3.0
Omalizumab 300mg	71	15.29	4.12	16.0	7.0	21.0	2.48	4.75	0.0	0.0	21.0	-12.81	5.64	0.67	-14.5	-21.0	0.0

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 24																	
Placebo	55	15.25	4.52	15.5	6.0	21.0	7.60	6.61	7.0	0.0	21.0	-7.64	6.85	0.92	-7.0	-21.0	6.0
Omalizumab 75mg	63	15.81	4.24	15.5	4.0	21.0	8.07	7.51	6.5	0.0	21.0	-7.74	7.17	0.90	-7.5	-21.0	5.5
Omalizumab 150mg	57	15.23	4.25	15.0	6.0	21.0	5.68	6.47	3.5	0.0	21.0	-9.55	6.43	0.85	-10.5	-21.0	5.0
Omalizumab 300mg	70	15.26	4.14	16.0	7.0	21.0	2.82	5.19	0.0	0.0	21.0	-12.43	5.97	0.71	-13.0	-21.0	2.0
Week 25																	
Placebo	52	15.34	4.38	15.8	7.0	21.0	7.89	6.00	7.0	0.0	21.0	-7.45	6.57	0.91	-7.3	-21.0	5.0
Omalizumab 75mg	60	15.70	4.22	15.5	4.0	21.0	8.66	7.17	7.3	0.0	21.0	-7.04	6.70	0.87	-6.8	-21.0	6.0
Omalizumab 150mg	57	15.32	4.32	15.0	6.0	21.0	6.85	6.55	6.0	0.0	21.0	-8.46	6.05	0.80	-8.5	-21.0	2.5
Omalizumab 300mg	69	15.28	4.17	16.0	7.0	21.0	3.04	5.17	0.0	0.0	21.0	-12.24	5.72	0.69	-12.5	-21.0	1.5
Week 26																	
Placebo	48	15.25	4.41	15.5	7.0	21.0	7.73	6.05	7.0	0.0	21.0	-7.52	7.00	1.01	-8.0	-21.0	4.0
Omalizumab 75mg	60	15.85	4.12	15.5	4.0	21.0	9.75	7.02	8.8	0.0	21.0	-6.10	6.81	0.88	-5.0	-21.0	6.0
Omalizumab 150mg	53	15.50	4.22	15.0	6.0	21.0	8.11	6.72	7.6	0.0	21.0	-7.39	6.63	0.91	-7.0	-21.0	8.0
Omalizumab 300mg	70	15.14	4.10	16.0	7.0	21.0	4.20	5.49	2.0	0.0	21.0	-10.93	6.03	0.72	-11.3	-21.0	5.5
Week 27																	
Placebo	49	15.32	4.39	16.0	7.0	21.0	7.71	5.90	7.5	0.0	21.0	-7.60	6.95	0.99	-6.0	-21.0	4.5
Omalizumab 75mg	59	15.91	4.14	15.5	4.0	21.0	10.52	7.20	10.0	0.0	21.0	-5.39	7.16	0.93	-4.5	-21.0	9.0
Omalizumab 150mg	52	15.16	4.26	15.0	6.0	21.0	8.16	6.79	7.3	0.0	21.0	-7.00	6.56	0.91	-5.3	-21.0	4.5
Omalizumab 300mg	67	15.13	4.18	16.0	7.0	21.0	5.26	6.19	3.0	0.0	21.0	-9.86	6.03	0.74	-11.0	-21.0	5.0
Week 28																	
Placebo	49	15.32	4.39	16.0	7.0	21.0	7.44	5.95	7.0	0.0	21.0	-7.88	6.59	0.94	-7.5	-21.0	2.5
Omalizumab 75mg	56	15.76	4.18	15.5	4.0	21.0	10.70	7.22	10.5	0.0	21.0	-5.06	7.19	0.96	-3.3	-21.0	6.5
Omalizumab 150mg	51	15.12	4.29	15.0	6.0	21.0	8.72	6.40	9.0	0.0	21.0	-6.40	6.38	0.89	-5.0	-21.0	5.0
Omalizumab 300mg	67	15.05	4.16	16.0	7.0	21.0	5.84	6.50	2.5	0.0	21.0	-9.22	6.30	0.77	-9.5	-21.0	7.0
Week 29																	
Placebo	47	15.10	4.34	15.0	7.0	21.0	7.41	6.17	7.0	0.0	21.0	-7.68	6.67	0.97	-7.0	-21.0	6.0
Omalizumab 75mg	56	15.85	4.18	15.5	4.0	21.0	10.64	7.13	9.4	0.0	21.0	-5.21	7.14	0.95	-3.3	-21.0	7.5
Omalizumab 150mg	51	15.11	4.29	15.0	6.0	21.0	9.00	7.04	8.5	0.0	21.0	-6.11	7.44	1.04	-4.5	-21.0	12.0
Omalizumab 300mg	64	15.05	4.20	16.0	7.0	21.0	6.38	6.29	6.3	0.0	21.0	-8.68	6.21	0.78	-9.0	-20.0	4.0

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 30																	
Placebo	46	14.98	4.32	15.0	7.0	21.0	6.55	5.57	7.0	0.0	20.0	-8.43	6.67	0.98	-7.3	-21.0	2.5
Omalizumab 75mg	54	15.77	4.19	15.5	4.0	21.0	10.33	6.84	10.8	0.0	21.0	-5.44	6.87	0.94	-4.6	-19.5	12.5
Omalizumab 150mg	51	15.11	4.29	15.0	6.0	21.0	8.32	7.03	7.0	0.0	21.0	-6.79	7.38	1.03	-5.0	-21.0	9.5
Omalizumab 300mg	62	15.04	4.23	16.0	7.0	21.0	7.77	7.39	7.0	0.0	21.0	-7.27	7.03	0.89	-7.0	-19.8	7.0
Week 31																	
Placebo	45	14.90	4.33	15.0	7.0	21.0	7.30	6.43	6.0	0.0	20.5	-7.60	7.56	1.13	-7.5	-21.0	7.5
Omalizumab 75mg	52	15.66	4.23	15.5	4.0	21.0	10.68	7.05	10.5	0.0	21.0	-4.98	7.27	1.01	-3.8	-19.0	12.5
Omalizumab 150mg	51	15.11	4.29	15.0	6.0	21.0	9.23	6.44	8.5	0.0	21.0	-5.87	6.36	0.89	-5.0	-21.0	5.0
Omalizumab 300mg	60	14.85	4.17	15.8	7.0	21.0	7.59	7.28	6.0	0.0	21.0	-7.26	7.10	0.92	-7.5	-20.0	8.5
Week 32																	
Placebo	45	14.90	4.33	15.0	7.0	21.0	7.75	6.43	7.0	0.0	19.0	-7.15	7.75	1.16	-5.5	-21.0	9.0
Omalizumab 75mg	51	15.67	4.28	15.5	4.0	21.0	10.48	6.76	10.0	0.0	21.0	-5.19	6.93	0.97	-5.0	-18.0	12.0
Omalizumab 150mg	50	15.12	4.33	15.0	6.0	21.0	8.63	6.58	7.8	0.0	21.0	-6.49	6.67	0.94	-6.0	-21.0	6.5
Omalizumab 300mg	58	14.73	4.17	15.5	7.0	21.0	8.18	7.36	7.0	0.0	21.0	-6.56	7.44	0.98	-6.8	-20.0	8.0
Week 33																	
Placebo	45	14.90	4.33	15.0	7.0	21.0	6.88	6.36	6.0	0.0	19.3	-8.02	7.73	1.15	-8.0	-21.0	10.5
Omalizumab 75mg	50	15.56	4.25	15.3	4.0	21.0	10.72	6.96	10.8	0.0	21.0	-4.84	6.70	0.95	-3.0	-17.0	9.0
Omalizumab 150mg	50	14.99	4.25	14.8	6.0	21.0	9.48	7.04	8.6	0.0	21.0	-5.51	6.64	0.94	-4.0	-21.0	7.0
Omalizumab 300mg	56	14.69	4.23	15.5	7.0	21.0	8.38	7.31	7.0	0.0	21.0	-6.31	7.60	1.02	-5.5	-21.0	7.5
Week 34																	
Placebo	47	15.11	4.36	15.0	7.0	21.0	7.03	6.80	7.0	0.0	21.0	-8.08	8.01	1.17	-7.5	-21.0	11.0
Omalizumab 75mg	49	15.57	4.29	15.5	4.0	21.0	10.53	6.68	9.0	0.0	21.0	-5.04	6.21	0.89	-2.5	-15.5	9.5
Omalizumab 150mg	50	15.12	4.33	15.0	6.0	21.0	9.51	6.83	9.3	0.0	21.0	-5.61	6.28	0.89	-4.8	-21.0	7.0
Omalizumab 300mg	54	14.61	4.21	15.5	7.0	21.0	8.56	7.11	8.8	0.0	21.0	-6.05	7.68	1.05	-5.0	-19.5	8.5
Week 35																	
Placebo	45	14.96	4.36	15.0	7.0	21.0	7.41	7.09	7.0	0.0	19.8	-7.55	8.05	1.20	-7.0	-21.0	12.5
Omalizumab 75mg	48	15.70	4.25	15.5	4.0	21.0	10.86	6.80	10.3	0.0	21.0	-4.84	6.38	0.92	-3.4	-17.5	11.5
Omalizumab 150mg	51	15.11	4.29	15.0	6.0	21.0	9.19	7.04	7.6	0.0	21.0	-5.91	6.57	0.92	-5.0	-21.0	7.0
Omalizumab 300mg	56	14.69	4.23	15.5	7.0	21.0	9.13	6.93	8.3	0.0	21.0	-5.56	7.33	0.98	-4.8	-21.0	8.0

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/12.2
Mean and Mean Change from Baseline in Weekly Size of Largest Hive Score by Study Week (Observed Data)
Modified Intention to Treat Patients

		Baseline					Value at Visit					Change from Baseline					
	n*	Mean	SD	Median	Min	Max	Mean	SD	Median	Min	Max	Mean	SD	SE	Median	Min	Max
Week 36																	
Placebo	46	15.07	4.40	15.0	7.0	21.0	6.88	6.66	7.0	0.0	21.0	-8.18	7.98	1.18	-7.5	-21.0	14.0
Omalizumab 75mg	48	15.70	4.25	15.5	4.0	21.0	10.46	6.70	9.8	0.0	21.0	-5.24	6.16	0.89	-4.0	-20.0	8.5
Omalizumab 150mg	51	15.11	4.29	15.0	6.0	21.0	9.73	7.34	7.9	0.0	21.0	-5.38	6.72	0.94	-4.5	-19.5	7.0
Omalizumab 300mg	56	14.69	4.23	15.5	7.0	21.0	9.08	7.22	8.0	0.0	21.0	-5.61	7.45	1.00	-5.0	-19.6	8.5
Week 37																	
Placebo	45	14.98	4.41	15.0	7.0	21.0	6.96	6.77	7.0	0.0	21.0	-8.02	7.97	1.19	-7.0	-21.0	14.0
Omalizumab 75mg	50	15.61	4.26	15.5	4.0	21.0	10.38	6.50	9.5	0.0	21.0	-5.23	5.80	0.82	-4.0	-17.0	4.5
Omalizumab 150mg	50	15.08	4.33	14.8	6.0	21.0	8.97	7.18	7.0	0.0	21.0	-6.12	6.66	0.94	-5.5	-20.5	6.5
Omalizumab 300mg	51	14.40	4.20	15.5	7.0	21.0	9.15	7.37	8.0	0.0	21.0	-5.25	7.62	1.07	-4.5	-19.5	8.5
Week 38																	
Placebo	44	14.90	4.42	15.0	7.0	21.0	6.64	6.47	6.3	0.0	21.0	-8.26	7.79	1.17	-8.3	-21.0	14.0
Omalizumab 75mg	48	15.49	4.29	15.3	4.0	21.0	9.60	6.45	9.3	0.0	21.0	-5.89	6.31	0.91	-6.0	-18.0	10.0
Omalizumab 150mg	50	15.08	4.33	14.8	6.0	21.0	8.85	7.35	7.3	0.0	21.0	-6.23	6.87	0.97	-6.0	-21.0	7.0
Omalizumab 300mg	52	14.53	4.26	15.5	7.0	21.0	9.16	7.22	8.0	0.0	21.0	-5.37	7.42	1.03	-3.3	-18.5	7.5
Week 39																	
Placebo	45	14.98	4.41	15.0	7.0	21.0	7.59	6.96	7.0	0.0	21.0	-7.39	8.02	1.19	-7.5	-21.0	12.0
Omalizumab 75mg	47	15.59	4.33	15.5	4.0	21.0	9.84	6.86	8.8	0.0	21.0	-5.74	6.16	0.90	-4.7	-18.7	8.0
Omalizumab 150mg	49	14.96	4.29	14.5	6.0	21.0	9.06	7.40	7.5	0.0	21.0	-5.90	6.72	0.96	-6.0	-20.5	7.8
Omalizumab 300mg	50	14.42	4.30	15.3	7.0	21.0	9.05	7.34	7.8	0.0	21.0	-5.38	7.65	1.08	-5.3	-19.5	10.5
Week 40																	
Placebo	41	15.26	4.18	15.0	7.0	21.0	6.99	6.37	7.0	0.0	18.9	-8.26	7.25	1.13	-8.0	-21.0	6.5
Omalizumab 75mg	46	15.76	4.21	15.5	4.0	21.0	9.51	6.67	8.8	0.0	21.0	-6.25	6.13	0.90	-4.8	-21.0	2.5
Omalizumab 150mg	49	15.08	4.37	14.5	6.0	21.0	9.05	7.31	7.5	0.0	21.0	-6.03	6.62	0.95	-6.0	-20.5	7.0
Omalizumab 300mg	47	14.48	4.29	15.0	7.0	21.0	9.38	7.47	8.0	0.0	21.0	-5.10	7.38	1.08	-5.0	-19.5	8.5

* Number of subjects with both baseline and visit values.
Baseline weekly size of largest hive score is calculated using eDiary data from the 7 days prior to the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_meanchg)
Database (CLOSED) Datasets (diaryeff)
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Table 14.2/14
Change from Baseline in Overall Dermatology Life Quality Index (DLQI) Score at Week 12 (BOCF Method)
Modified Intention to Treat Patients

	Placebo (n=80)	Omalizumab 75mg (n=77)	Omalizumab 150mg (n=80)	Omalizumab 300mg (n=81)
Change from Baseline in Overall Dermatology Life Quality Index (DLQI) Score at Week 12(BOCF Method)				
n	79	75	80	81
Mean (SD)	-4.78 (6.11)	-5.60 (6.05)	-6.96 (7.15)	-9.23 (7.49)
SE	0.69	0.70	0.80	0.83
Median	-3.0	-4.0	-6.5	-7.0
Range	-24.0 - 9.0	-24.0 - 8.0	-30.0 - 9.0	-26.0 - 5.0
95% CI of the Mean	(-6.15, -3.42)	(-6.99, -4.21)	(-8.55, -5.37)	(-10.89, -7.58)
Treatment Difference in LS Means* (relative to the Placebo group)		-0.80	-2.04	-4.69
95% CI of the LS Means Difference		(-2.66, 1.06)	(-4.02, -0.07)	(-6.62, -2.75)
p-value^		0.3964	0.0430	<.0001

BOCF = Baseline observation carried forward. Baseline overall DLQI score is the measurement taken prior to dosing on Day 1.
Missing Wk 12 overall DLQI scores are imputed using baseline scores.
*The LS mean was estimated using ANCOVA model. The strata are for baseline
overall DLQI score (< median vs. >=median), and baseline weight (< 80 kg vs. >= 80 kg).
^ p-value is derived from ANCOVA t-test.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_derm_wk12_bocf)
Database (CLOSED) Datasets (pat dlqieff)
: Generated 25JAN13 14:02 Page 1 of 1

Table 14.2/54
Serum Omalizumab Concentration (ng/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Placebo	Day1 (Predose)	4	73	0	8.01	56.8	0.00	0.00	494
	Week 12	18	44	0	NR	NR	90.3	NR	20000
	Week 24	4	59	0	NR	NR	238	NR	1430
	Week 40	7	54	0	NR	NR	60.6	NR	19600
	Early Term	4	6	0	NR	NR	133	NR	158
Omalizumab 75mg	Day1 (Predose)	8	61	0	29.7	130	0.00	0.00	943
	Week 12	62	0	0	7410	4550	6870	408	22800
	Week 24	62	0	0	7630	4200	7250	1400	22800
	Week 40	48	8	0	346	411	176	14.0	1950
	Early Term	7	0	0	3870	3450	5320	225	8330
Omalizumab 150mg	Day1 (Predose)	8	74	0	7.42	24.3	0.00	0.00	115
	Week 12	72	0	0	13300	7300	13000	1300	29500
	Week 24	73	1	0	14000	8790	13200	14.0	37100

Values less than reportable (LTR) on Day 0 were set to 0. All other LTR values were handled as follows: For a given treatment and sampling day, if one-third or fewer values were LTR, they were set to 14, which was half the limit of quantification (0.5 * 28) and all summary statistics were computed. If more than one-third of the values were LTR, only the median and maximum, as appropriate, were calculated, and the rest of the summary statistics were non-reportable (NR).
For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_pk_free_total)
Database (CLOSED) Datasets (pkconc)
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Table 14.2/54
Serum Omalizumab Concentration (ng/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Omalizumab 150mg	Week 40	61	9	0	1960	10200	378	14.0	85600
	Early Term	14	0	0	7910	6650	8710	155	20200
Omalizumab 300mg	Day1 (Predose)	3	78	0	4.58	26.0	0.00	0.00	174
	Week 12	72	0	0	30600	15600	28400	3820	76600
	Week 24	72	0	0	30900	15300	29300	929	83300
	Week 40	67	0	0	2010	2720	975	46.7	17800
	Early Term	8	0	0	12900	9470	10100	3190	29900

Values less than reportable (LTR) on Day 0 were set to 0. All other LTR values were handled as follows: For a given treatment and sampling day, if one-third or fewer values were LTR, they were set to 14, which was half the limit of quantification (0.5 * 28) and all summary statistics were computed. If more than one-third of the values were LTR, only the median and maximum, as appropriate, were calculated, and the rest of the summary statistics were non-reportable (NR).
For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_pk_free_total)
Database (CLOSED) Datasets (pkconc)
: Generated 25JAN13 10:56 Page 2 of 2

Table 14.2/55.1
Serum Total IgE Concentration (IU/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Placebo	Day1 (Predose)	75	2	0	161	215	92.0	1.00	1010
	Week 12	60	3	0	166	237	97.0	1.00	1340
	Week 24	59	2	0	179	393	66.0	1.00	2360
	Week 40	59	3	0	153	258	61.0	1.00	1430
	Early Term	11	0	0	134	128	77.0	32.0	475
Omalizumab 75mg	Day1 (Predose)	68	1	0	203	346	91.0	1.00	2030
	Week 12	61	1	0	444	667	258	1.00	4290
	Week 24	61	1	0	464	662	261	1.00	3800
	Week 40	55	1	0	209	385	83.0	1.00	2100
	Early Term	7	0	0	391	409	202	23.0	1080
Omalizumab 150mg	Day1 (Predose)	76	3	1	216	590	71.0	1.00	5000
	Week 12	66	3	1	461	683	282	1.00	5000
	Week 24	70	3	1	533	849	289	1.00	5000

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 1,i.e. 1/2 the limit of quantification(0.5*2) or if <=1/3rd values were GTR, they were set to 5000,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_pk_free_total)
Database (CLOSED) Datasets (pkconc)
: Generated 25JAN13 10:56 Page 1 of 2

Table 14.2/55.1
Serum Total IgE Concentration (IU/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Omalizumab 150mg	Week 40	67	2	1	262	684	89.5	1.00	5000
	Early Term	14	0	0	172	193	80.0	5.00	610
Omalizumab 300mg	Day1 (Predose)	79	1	0	153	285	85.5	1.00	2330
	Week 12	70	0	1	508	693	327	6.00	5000
	Week 24	70	0	1	470	664	315	5.00	5000
	Week 40	67	0	0	206	269	150	2.00	1860
	Early Term	8	0	0	204	243	76.0	2.00	662

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 1,i.e. 1/2 the limit of quantification(0.5*2) or if <=1/3rd values were GTR, they were set to 5000,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_pk_free_total)
Database (CLOSED) Datasets (pkconc)
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Table 14.2/55.2
Serum Total IgE Concentration (IU/mL) Change from Baseline
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	n	Mean	SD	Median	Min	Max
Placebo	Day1 (Predose)	77	0.00	0.00	0.00	0.00	0.00
	Week 12	60	-3.55	103	1.00	-400	330
	Week 24	60	16.9	235	-5.00	-434	1400
	Week 40	60	-5.32	111	-6.50	-433	420
	Early Term	11	19.5	47.4	13.0	-31.0	148
Omalizumab 75mg	Day1 (Predose)	69	0.00	0.00	0.00	0.00	0.00
	Week 12	61	244	344	161	-51.0	2260
	Week 24	61	256	343	154	-95.0	1770
	Week 40	55	5.47	79.8	4.00	-380	280
	Early Term	7	174	187	126	-13.0	428
Omalizumab 150mg	Day1 (Predose)	80	0.00	0.00	0.00	0.00	0.00
	Week 12	64	251	276	190	-14.0	1280
	Week 24	69	241	320	172	-670	1720

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 1,i.e. 1/2 the limit of quantification(0.5*2) or if <=1/3rd values were GTR, they were set to 5000,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_chgfmbs_free_total)
Database (CLOSED) Datasets (pkconc)
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Table 14.2/55.2
Serum Total IgE Concentration (IU/mL) Change from Baseline
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	n	Mean	SD	Median	Min	Max
Omalizumab 150mg	Week 40	65	-54.7	290	3.00	-2020	178
	Early Term	12	135	172	69.5	-4.00	495
Omalizumab 300mg	Day1 (Predose)	80	0.00	0.00	0.00	0.00	0.00
	Week 12	70	342	422	235	-81.0	2670
	Week 24	70	307	383	206	3.00	2670
	Week 40	66	39.1	106	25.0	-470	313
	Early Term	8	140	168	59.0	1.00	457

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 1,i.e. 1/2 the limit of quantification(0.5*2) or if <=1/3rd values were GTR, they were set to 5000,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_chgfmbs_free_total)
Database (CLOSED) Datasets (pkconc)
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Table 14.2/56.1
Serum Free IgE Concentration (IU/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Placebo	Day1 (Predose)	35	1	41	NR	NR	14.5	0.415	NR
	Week 12	25	3	35	NR	NR	13.0	0.415	NR
	Week 24	30	2	31	NR	NR	13.4	0.415	NR
	Week 40	32	4	26	NR	NR	11.0	0.415	NR
	Early Term	4	0	6	NR	NR	42.2	23.8	NR
Omalizumab 75mg	Day1 (Predose)	35	1	33	NR	NR	17.9	0.415	NR
	Week 12	49	4	9	23.3	21.6	16.6	0.415	62.0
	Week 24	50	4	9	24.8	21.8	15.5	0.415	62.0
	Week 40	29	1	26	NR	NR	20.0	0.415	NR
	Early Term	3	0	4	NR	NR	2.10	1.04	NR
Omalizumab 150mg	Day1 (Predose)	33	6	43	NR	NR	9.71	0.415	NR
	Week 12	57	8	6	17.7	18.2	12.6	0.415	62.0
	Week 24	60	7	7	19.3	20.2	10.6	0.415	62.0

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 0.415,i.e. 1/2 the limit of quantification(0.5*0.83) or if <=1/3rd values were GTR, they were set to 62.0,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_pk_free_total)
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Table 14.2/56.1
Serum Free IgE Concentration (IU/mL)
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	Number of Measurable Samples	Number of LTR	Number of GTR	Mean	SD	Median	Min	Max
Omalizumab 150mg	Week 40	31	4	34	NR	NR	11.2	0.415	NR
	Early Term	10	3	1	22.5	23.2	14.0	0.415	62.0
Omalizumab 300mg	Day1 (Predose)	37	1	43	NR	NR	10.9	0.415	NR
	Week 12	64	6	1	9.01	10.2	6.03	0.415	62.0
	Week 24	66	5	1	8.11	9.52	5.21	0.415	62.0
	Week 40	38	1	28	NR	NR	16.0	0.415	NR
	Early Term	7	1	0	15.7	23.8	3.85	0.415	60.7

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 0.415,i.e. 1/2 the limit of quantification(0.5*0.83) or if <=1/3rd values were GTR, they were set to 62.0,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.
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Database (CLOSED) Datasets (pkconc)
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Table 14.2/56.2
Serum Free IgE Concentration (IU/mL) Change from Baseline
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	n	Mean	SD	Median	Min	Max
Placebo	Day1 (Predose)	36	NR	NR	-7.31	-907	NR
	Week 12	25	NR	NR	-8.80	-116	NR
	Week 24	31	NR	NR	-9.79	-444	NR
	Week 40	34	NR	NR	-12.9	-439	NR
	Early Term	4	NR	NR	-1.86	-38.1	NR
Omalizumab 75mg	Day1 (Predose)	36	NR	NR	-4.55	-184	NR
	Week 12	61	-182	351	-57.4	-1970	-0.585
	Week 24	62	-185	348	-63.7	-1970	-0.585
	Week 40	30	NR	NR	-8.33	-541	NR
	Early Term	3	NR	NR	-8.96	-60.2	NR
Omalizumab 150mg	Day1 (Predose)	38	NR	NR	-3.55	-54.3	NR
	Week 12	65	-125	189	-58.9	-1190	1.87
	Week 24	69	-216	621	-65.5	-4940	3.35

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 0.415,i.e. 1/2 the limit of quantification(0.5*0.83) or if <=1/3rd values were GTR, they were set to 62.0,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.Change from baseline of free IgE uses baseline total IgE levels as baseline.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_chgfmbs_free_total)
Database (CLOSED) Datasets (pkconc)
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Table 14.2/56.2
Serum Free IgE Concentration (IU/mL) Change from Baseline
Pharmacokinetic Evaluable Patients

Treatment Dose Level	Visit	n	Mean	SD	Median	Min	Max
Omalizumab 150mg	Week 40	33	NR	NR	-4.91	-83.1	NR
	Early Term	12	-33.8	39.7	-19.3	-95.7	18.0
Omalizumab 300mg	Day1 (Predose)	38	NR	NR	-6.24	-96.8	NR
	Week 12	70	-155	293	-84.1	-2270	-1.59
	Week 24	71	-152	292	-80.3	-2270	-0.269
	Week 40	38	NR	NR	-11.9	-187	NR
	Early Term	8	-48.7	57.1	-15.7	-144	-0.585

For a given treatment and sampling day,if <=1/3rd values were LTR,they were set to 0.415,i.e. 1/2 the limit of quantification(0.5*0.83) or if <=1/3rd values were GTR, they were set to 62.0,i.e. the upper limit of quantification and all summary statistics were computed. If >1/3rd of the values were LTR,only the median and maximum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR).If >1/3rd of the values were GTR,only the median and minimum,as appropriate,were calculated,and the rest of the summary statistics were non-reportable (NR).If >1/3rd of the values were LTR and >1/3rd of the values were GTR,then only the median,as appropriate,were calculated,and the rest of the summary statistics were non-reportable(NR). For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.Change from baseline of free IgE uses baseline total IgE levels as baseline.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_pkdesc_chgfmbs_free_total)
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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
LEUKOCYTOSES NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOCYTOSIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEUTROPHILIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEUTROPENIAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NEUTROPENIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THROMBOCYTOPENIAS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THROMBOCYTOPENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CARDIAC DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
RATE AND RHYTHM DISORDERS NEC	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ARRHYTHMIA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BRADYCARDIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ISCHAEMIC CORONARY ARTERY DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGINA UNSTABLE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
CENTRAL NERVOUS SYSTEM DISORDERS CONGENITAL NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SYRINGOMYELIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS					
COAGULATION DISORDERS CONGENITAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FACTOR V DEFICIENCY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
INNER EAR SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
VERTIGO	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
TINNITUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ENDOCRINE DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THYROID DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GOITRE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EYE DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	2 (2.3%)	3 (3.7%)	6 (1.9%)
CONJUNCTIVAL INFECTIONS, IRRITATIONS AND INFLAMMATIONS	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
CONJUNCTIVITIS	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
LACRIMAL DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DRY EYE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OCULAR DISORDERS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EYE PAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VISUAL DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VISUAL IMPAIRMENT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS					
- Overall -	6 (7.5%)	7 (10.0%)	5 (5.7%)	5 (6.2%)	23 (7.2%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	1 (1.3%)	3 (4.3%)	1 (1.1%)	1 (1.2%)	6 (1.9%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
CONSTIPATION	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
ABDOMINAL PAIN UPPER	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
ABDOMINAL PAIN	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
ABDOMINAL PAIN LOWER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL PAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GASTROINTESTINAL SIGNS AND SYMPTOMS NEC	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
ABDOMINAL DISCOMFORT	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
DENTAL PAIN AND SENSATION DISORDERS	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
TOOTHACHE	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
DIARRHOEA (EXCL INFECTIVE)	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
DIARRHOEA	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
NAUSEA AND VOMITING SYMPTOMS	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
NAUSEA	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
GASTRITIS (EXCL INFECTIVE)	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GASTRITIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL HAEMORRHAGES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL BLEEDING	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INTESTINAL HAEMORRHAGES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RECTAL HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS					
ORAL SOFT TISSUE PAIN AND PARAESTHESIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ODYNOPHAGIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LIP SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONGUE SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TONGUE COATED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	2 (2.5%)	3 (4.3%)	7 (8.0%)	7 (8.6%)	19 (6.0%)
OEDEMA NEC	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
OEDEMA PERIPHERAL	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
FEBRILE DISORDERS	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
PYREXIA	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
INJECTION SITE REACTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	3 (3.7%)	5 (1.6%)
INJECTION SITE HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE PAIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJECTION SITE PRURITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE URTICARIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GENERAL SIGNS AND SYMPTOMS NEC	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
INFLUENZA LIKE ILLNESS	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ASTHENIC CONDITIONS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ASTHENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FATIGUE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
MASS CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CYST	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PAIN AND DISCOMFORT NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CHEST PAIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS					
- Overall -	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
FOOD ALLERGY	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
DRUG HYPERSENSITIVITY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGIC CONDITIONS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERSENSITIVITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	22 (27.5%)	20 (28.6%)	32 (36.8%)	16 (19.8%)	90 (28.3%)
UPPER RESPIRATORY TRACT INFECTIONS	15 (18.8%)	12 (17.1%)	18 (20.7%)	13 (16.0%)	58 (18.2%)
NASOPHARYNGITIS	10 (12.5%)	3 (4.3%)	11 (12.6%)	9 (11.1%)	33 (10.4%)
SINUSITIS	4 (5.0%)	5 (7.1%)	4 (4.6%)	3 (3.7%)	16 (5.0%)
UPPER RESPIRATORY TRACT INFECTION	3 (3.8%)	3 (4.3%)	3 (3.4%)	1 (1.2%)	10 (3.1%)
PHARYNGITIS	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
RHINITIS	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
TONSILLITIS	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
ACUTE SINUSITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
CHRONIC SINUSITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	5 (6.3%)	4 (5.7%)	4 (4.6%)	1 (1.2%)	14 (4.4%)
BRONCHITIS	5 (6.3%)	4 (5.7%)	2 (2.3%)	1 (1.2%)	12 (3.8%)
ATYPICAL PNEUMONIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LOWER RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT INFECTIONS	2 (2.5%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	9 (2.8%)
URINARY TRACT INFECTION	2 (2.5%)	1 (1.4%)	4 (4.6%)	1 (1.2%)	8 (2.5%)
CYSTITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VIRAL INFECTIONS NEC	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
GASTROENTERITIS VIRAL	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
BRONCHITIS VIRAL	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL VIRAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR INFECTIONS	3 (3.8%)	1 (1.4%)	(0.0%)	1 (1.2%)	5 (1.6%)
EAR INFECTION	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
OTITIS MEDIA	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
FUNGAL INFECTIONS NEC	(0.0%)	(0.0%)	4 (4.6%)	(0.0%)	4 (1.3%)
FUNGAL INFECTION	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
ONYCHOMYCOSIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
APPENDICITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROENTERITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STREPTOCOCCAL INFECTIONS	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
PHARYNGITIS STREPTOCOCCAL	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
BACTERIAL INFECTIONS NEC	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
PNEUMONIA BACTERIAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VAGINITIS BACTERIAL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
HERPES VIRAL INFECTIONS	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
HERPES ZOSTER	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL HERPES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INFECTIONS NEC	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
BREAST INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BREAST ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CANDIDA INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ORAL CANDIDIASIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
TOOTH INFECTION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INFLUENZA VIRAL INFECTIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INFLUENZA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL SKIN INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
- Overall -	2 (2.5%)	2 (2.9%)	(0.0%)	5 (6.2%)	9 (2.8%)
LIMB INJURIES NEC (INCL TRAUMATIC AMPUTATION)	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
MENISCUS LESION	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
JOINT INJURY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LIMB INJURY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LOWER LIMB FRACTURES AND DISLOCATIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANKLE FRACTURE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
MUSCLE, TENDON AND LIGAMENT INJURIES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LIGAMENT SPRAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NON-SITE SPECIFIC INJURIES NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FALL	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PERIPHERAL NERVE INJURIES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MEDIAN NERVE INJURY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SITE SPECIFIC INJURIES NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TOOTH FRACTURE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN INJURIES NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN INJURY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UPPER LIMB FRACTURES AND DISLOCATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RADIUS FRACTURE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INVESTIGATIONS					
- Overall -	2 (2.5%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	7 (2.2%)
PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
WEIGHT DECREASED	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
WEIGHT INCREASED	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
CARBOHYDRATE TOLERANCE ANALYSES (INCL DIABETES)	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BLOOD GLUCOSE INCREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SERUM FERRITIN DECREASED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RED BLOOD CELL ANALYSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HAEMOGLOBIN DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
DIABETES MELLITUS (INCL SUBTYPES)	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DIABETES MELLITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TYPE 2 DIABETES MELLITUS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ELEVATED TRIGLYCERIDES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERTRIGLYCERIDAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FLUID INTAKE INCREASED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
POLYDIPSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIC CONDITIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERLIPIDAEMIAS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERLIPIDAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	2 (2.5%)	7 (10.0%)	12 (13.8%)	9 (11.1%)	30 (9.4%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN	2 (2.5%)	3 (4.3%)	5 (5.7%)	2 (2.5%)	12 (3.8%)
AND DISCOMFORT					
BACK PAIN	2 (2.5%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	6 (1.9%)
PAIN IN EXTREMITY	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
MUSCULOSKELETAL PAIN	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	2 (2.9%)	5 (5.7%)	4 (4.9%)	11 (3.5%)
ARTHRALGIA	(0.0%)	1 (1.4%)	5 (5.7%)	3 (3.7%)	9 (2.8%)
JOINT SWELLING	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
MUSCLE PAINS	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
MYALGIA	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
BONE RELATED SIGNS AND SYMPTOMS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
COCCYDYNIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSAL DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC PROTRUSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE SPASMS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE WEAKNESS CONDITIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULAR WEAKNESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE INFECTIONS AND INFLAMMATIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PLANTAR FASCIITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OSTEOARTHROPATHIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
OSTEOARTHRITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TENDON DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TENDONITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)					
- Overall -	2 (2.5%)	3 (4.3%)	(0.0%)	1 (1.2%)	6 (1.9%)
BONE NEOPLASMS BENIGN (EXCL CYSTS)	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMANGIOMA OF BONE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
BREAST AND NIPPLE NEOPLASMS BENIGN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LIPOMA OF BREAST	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

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Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)					
ENDOCRINE NEOPLASMS BENIGN NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PARATHYROID TUMOUR BENIGN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEUROMAS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NEUROMA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN NEOPLASMS BENIGN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN PAPILLOMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE NEOPLASMS BENIGN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE LEIOMYOMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS					
- Overall -	4 (5.0%)	7 (10.0%)	14 (16.1%)	8 (9.9%)	33 (10.4%)
HEADACHES NEC	2 (2.5%)	4 (5.7%)	10 (11.5%)	5 (6.2%)	21 (6.6%)
HEADACHE	2 (2.5%)	4 (5.7%)	8 (9.2%)	5 (6.2%)	19 (6.0%)
SINUS HEADACHE	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	2 (2.5%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
DIZZINESS	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
PRESYNCOPE	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
MIGRAINE HEADACHES	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
MIGRAINE	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
PARAESTHESIAS AND DYSAESTHESIAS	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HYPERAESTHESIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PARAESTHESIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MONONEUROPATHIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARPAL TUNNEL SYNDROME	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NERVOUS SYSTEM DISORDERS					
SENSORY ABNORMALITIES NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYPOAESTHESIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SPINAL CORD AND NERVE ROOT DISORDERS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NERVE ROOT LESION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PSYCHIATRIC DISORDERS					
- Overall -	2 (2.5%)	1 (1.4%)	5 (5.7%)	1 (1.2%)	9 (2.8%)
ANXIETY SYMPTOMS	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
ANXIETY	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
INSOMNIA	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
AFFECT ALTERATIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
AFFECT LABILITY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INCREASED PHYSICAL ACTIVITY LEVELS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESTLESSNESS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDERS AND SYMPTOMS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PANIC ATTACKS AND DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PANIC ATTACK	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SLEEP DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SLEEP DISORDER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RENAL AND URINARY DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RENAL AND URINARY DISORDERS					
URINARY ABNORMALITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LEUKOCYTURIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT SIGNS AND SYMPTOMS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
POLYURIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
- Overall -	3 (3.8%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	8 (2.5%)
CERVIX DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
CERVICAL DYSPLASIA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BENIGN AND MALIGNANT BREAST NEOPLASMS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BREAST CYST	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MENSTRUATION AND UTERINE BLEEDING NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DYSMENORRHOEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MENSTRUATION WITH INCREASED BLEEDING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MENORRHAGIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
REPRODUCTIVE TRACT SIGNS AND SYMPTOMS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PELVIC PAIN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UTERINE ENLARGEMENT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VULVOVAGINAL CYSTS AND NEOPLASMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VAGINAL CYST	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	10 (12.5%)	5 (7.1%)	12 (13.8%)	4 (4.9%)	31 (9.7%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
OROPHARYNGEAL PAIN	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
NASAL CONGESTION AND INFLAMMATIONS	2 (2.5%)	2 (2.9%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
NASAL CONGESTION	2 (2.5%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
RHINITIS ALLERGIC	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
BRONCHOSPASM AND OBSTRUCTION	3 (3.8%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	8 (2.5%)
ASTHMA	2 (2.5%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	6 (1.9%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
WHEEZING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
COUGHING AND ASSOCIATED SYMPTOMS	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
COUGH	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PARANASAL SINUS HYPERSECRETION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	13 (16.3%)	13 (18.6%)	10 (11.5%)	9 (11.1%)	45 (14.2%)
URTICARIAS	8 (10.0%)	9 (12.9%)	5 (5.7%)	3 (3.7%)	25 (7.9%)
URTICARIA	6 (7.5%)	5 (7.1%)	4 (4.6%)	2 (2.5%)	17 (5.3%)
IDIOPATHIC URTICARIA	2 (2.5%)	5 (7.1%)	1 (1.1%)	1 (1.2%)	9 (2.8%)
ANGIOEDEMAS	5 (6.3%)	(0.0%)	(0.0%)	3 (3.7%)	8 (2.5%)
ANGIOEDEMA	3 (3.8%)	(0.0%)	(0.0%)	3 (3.7%)	6 (1.9%)
SWELLING FACE	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
PRURITUS NEC	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
PRURITUS	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Safety-Evaluable Patients

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SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
ALOPECIAS	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
ALOPECIA	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
MADAROSIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DERMATITIS AND ECZEMA	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
ECZEMA	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DERMATITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DERMATITIS CONTACT	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
APOCRINE AND ECCRINE GLAND DISORDERS	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
HIDRADENITIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERHIDROSIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DERMAL AND EPIDERMAL CONDITIONS NEC	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DRY SKIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PAIN OF SKIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RASHES, ERUPTIONS AND EXANTHEMS NEC	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
RASH	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RASH MACULO-PAPULAR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EXFOLIATIVE CONDITIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN EXFOLIATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NAIL AND NAIL BED CONDITIONS (EXCL INFECTIONS AND INFESTATIONS)	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NAIL DYSTROPHY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PAPULOSQUAMOUS CONDITIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ERYTHEMA ANNULARE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PURPURA AND RELATED CONDITIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ECCHYMOSIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Table 14.3/9
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SURGICAL AND MEDICAL PROCEDURES					
- Overall -	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
DENTAL OPERATION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
TOOTH EXTRACTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TOOTH REPAIR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EYELID THERAPEUTIC PROCEDURES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
EYELID OPERATION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
JOINT THERAPEUTIC PROCEDURES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
KNEE OPERATION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VASCULAR DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HYPERTENSION	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
PERIPHERAL VASCULAR DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HOT FLUSH	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/2
Overall AE Profile: Adverse Events, Deaths, and Withdrawals by Study Treatment
Safety-Evaluable Patients

	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Total number of patients with at least one AE	53 (66.3%)	55 (78.6%)	72 (82.8%)	57 (70.4%)	237 (74.5%)
Total number of AEs	180	164	241	168	753
Total number of deaths	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Total number of patients withdrawn from study due to an AE	2 (2.5%)	(0.0%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
Total number of patients with at least one					
Serious AE	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
Serious AE leading to withdrawal from treatment	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
Serious AE leading to dose held	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Serious AE suspected to be caused by study drug	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
AE leading to withdrawal from treatment	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)
AE leading to dose held	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
AE suspected to be caused by study drug	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
Severe AE	8 (10.0%)	7 (10.0%)	8 (9.2%)	13 (16.0%)	36 (11.3%)

Includes adverse events with onset dates on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_ovrl)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	-Total-	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
	Mild	18 (22.5%)	20 (28.6%)	31 (35.6%)	18 (22.2%)	87 (27.4%)
	Moderate	15 (18.8%)	16 (22.9%)	24 (27.6%)	25 (30.9%)	80 (25.2%)
	Severe	8 (10.0%)	5 (7.1%)	5 (5.7%)	3 (3.7%)	21 (6.6%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
LEUKOCYTOSES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEUTROPENIAS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THROMBOCYTOPENIAS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CARDIAC DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RATE AND RHYTHM DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
CARDIAC DISORDERS						
ISCHAEMIC CORONARY ARTERY DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS						
- Overall -	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
CENTRAL NERVOUS SYSTEM DISORDERS CONGENITAL NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
COAGULATION DISORDERS CONGENITAL	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INNER EAR SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ENDOCRINE DISORDERS						
- Overall -	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THYROID DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
EYE DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	3 (3.7%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
CONJUNCTIVAL INFECTIONS, IRRITATIONS AND INFLAMMATIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
LACRIMAL DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OCULAR DISORDERS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VISUAL DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS						
- Overall -	-Total-	6 (7.5%)	7 (10.0%)	5 (5.7%)	5 (6.2%)	23 (7.2%)
	Mild	6 (7.5%)	5 (7.1%)	3 (3.4%)	3 (3.7%)	17 (5.3%)
	Moderate	(0.0%)	2 (2.9%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS						
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	-Total-	1 (1.3%)	3 (4.3%)	1 (1.1%)	1 (1.2%)	6 (1.9%)
	Mild	1 (1.3%)	3 (4.3%)	(0.0%)	1 (1.2%)	5 (1.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DENTAL PAIN AND SENSATION DISORDERS	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DIARRHOEA (EXCL INFECTIVE)	-Total-	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
NAUSEA AND VOMITING SYMPTOMS	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
GASTRITIS (EXCL INFECTIVE)	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL HAEMORRHAGES	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS						
INTESTINAL HAEMORRHAGES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ORAL SOFT TISSUE PAIN AND PARAESTHESIA	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONGUE SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
- Overall -	-Total-	2 (2.5%)	3 (4.3%)	7 (8.0%)	7 (8.6%)	19 (6.0%)
	Mild	1 (1.3%)	2 (2.9%)	3 (3.4%)	3 (3.7%)	9 (2.8%)
	Moderate	1 (1.3%)	(0.0%)	4 (4.6%)	4 (4.9%)	9 (2.8%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
OEDEMA NEC	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
FEBRILE DISORDERS	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE REACTIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	3 (3.7%)	5 (1.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
GENERAL SIGNS AND SYMPTOMS NEC	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ASTHENIC CONDITIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
MASS CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PAIN AND DISCOMFORT NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS						
- Overall -	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	-Total-	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGIC CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
- Overall -	-Total-	22 (27.5%)	20 (28.6%)	32 (36.8%)	16 (19.8%)	90 (28.3%)
	Mild	13 (16.3%)	14 (20.0%)	21 (24.1%)	12 (14.8%)	60 (18.9%)
	Moderate	9 (11.3%)	6 (8.6%)	10 (11.5%)	4 (4.9%)	29 (9.1%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UPPER RESPIRATORY TRACT INFECTIONS	-Total-	15 (18.8%)	12 (17.1%)	18 (20.7%)	13 (16.0%)	58 (18.2%)
	Mild	10 (12.5%)	11 (15.7%)	12 (13.8%)	11 (13.6%)	44 (13.8%)
	Moderate	5 (6.3%)	1 (1.4%)	6 (6.9%)	2 (2.5%)	14 (4.4%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	-Total-	5 (6.3%)	4 (5.7%)	4 (4.6%)	1 (1.2%)	14 (4.4%)
	Mild	3 (3.8%)	1 (1.4%)	3 (3.4%)	(0.0%)	7 (2.2%)
	Moderate	2 (2.5%)	3 (4.3%)	1 (1.1%)	1 (1.2%)	7 (2.2%)
URINARY TRACT INFECTIONS	-Total-	2 (2.5%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	9 (2.8%)
	Mild	2 (2.5%)	(0.0%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
VIRAL INFECTIONS NEC	-Total-	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
	Mild	2 (2.5%)	1 (1.4%)	2 (2.3%)	(0.0%)	5 (1.6%)
	Moderate	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
EAR INFECTIONS	-Total-	3 (3.8%)	1 (1.4%)	(0.0%)	1 (1.2%)	5 (1.6%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Moderate	3 (3.8%)	(0.0%)	(0.0%)	(0.0%)	3 (0.9%)
FUNGAL INFECTIONS NEC	-Total-	(0.0%)	(0.0%)	4 (4.6%)	(0.0%)	4 (1.3%)
	Mild	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STREPTOCOCCAL INFECTIONS	-Total-	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
BACTERIAL INFECTIONS NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HERPES VIRAL INFECTIONS	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INFECTIONS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BREAST INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CANDIDA INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

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Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
INFLUENZA VIRAL INFECTIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
- Overall -	-Total-	2 (2.5%)	2 (2.9%)	(0.0%)	5 (6.2%)	9 (2.8%)
	Mild	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
	Moderate	1 (1.3%)	2 (2.9%)	(0.0%)	3 (3.7%)	6 (1.9%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LIMB INJURIES NEC (INCL TRAUMATIC AMPUTATION)	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
LOWER LIMB FRACTURES AND DISLOCATIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCLE, TENDON AND LIGAMENT INJURIES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NON-SITE SPECIFIC INJURIES NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PERIPHERAL NERVE INJURIES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
SITE SPECIFIC INJURIES NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN INJURIES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UPPER LIMB FRACTURES AND DISLOCATIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INVESTIGATIONS						
- Overall -	-Total-	2 (2.5%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	7 (2.2%)
	Mild	2 (2.5%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	7 (2.2%)
PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
CARBOHYDRATE TOLERANCE ANALYSES (INCL DIABETES)	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RED BLOOD CELL ANALYSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class / High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
METABOLISM AND NUTRITION DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DIABETES MELLITUS (INCL SUBTYPES)	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ELEVATED TRIGLYCERIDES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FLUID INTAKE INCREASED	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIC CONDITIONS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERLIPIDAEMIAS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
- Overall -	-Total-	2 (2.5%)	7 (10.0%)	12 (13.8%)	9 (11.1%)	30 (9.4%)
	Mild	(0.0%)	5 (7.1%)	4 (4.6%)	1 (1.2%)	10 (3.1%)
	Moderate	2 (2.5%)	1 (1.4%)	6 (6.9%)	7 (8.6%)	16 (5.0%)
	Severe	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	-Total-	2 (2.5%)	3 (4.3%)	5 (5.7%)	2 (2.5%)	12 (3.8%)
	Mild	(0.0%)	3 (4.3%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Moderate	2 (2.5%)	(0.0%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Severe	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
JOINT RELATED SIGNS AND SYMPTOMS	-Total-	(0.0%)	2 (2.9%)	5 (5.7%)	4 (4.9%)	11 (3.5%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	3 (3.4%)	3 (3.7%)	6 (1.9%)
	Severe	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
MUSCLE PAINS	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
BONE RELATED SIGNS AND SYMPTOMS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSAL DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE WEAKNESS CONDITIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE INFECTIONS AND INFLAMMATIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
OSTEOARTHROPATHIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TENDON DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)						
- Overall -	-Total-	2 (2.5%)	3 (4.3%)	(0.0%)	1 (1.2%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	2 (2.5%)	2 (2.9%)	(0.0%)	1 (1.2%)	5 (1.6%)
BONE NEOPLASMS BENIGN (EXCL CYSTS)	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
BREAST AND NIPPLE NEOPLASMS BENIGN	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ENDOCRINE NEOPLASMS BENIGN NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEUROMAS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN NEOPLASMS BENIGN	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE NEOPLASMS BENIGN	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NERVOUS SYSTEM DISORDERS						
- Overall -	-Total-	4 (5.0%)	7 (10.0%)	14 (16.1%)	8 (9.9%)	33 (10.4%)
	Mild	3 (3.8%)	6 (8.6%)	10 (11.5%)	5 (6.2%)	24 (7.5%)
	Moderate	(0.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	7 (2.2%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HEADACHES NEC	-Total-	2 (2.5%)	4 (5.7%)	10 (11.5%)	5 (6.2%)	21 (6.6%)
	Mild	1 (1.3%)	4 (5.7%)	8 (9.2%)	3 (3.7%)	16 (5.0%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	-Total-	2 (2.5%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
	Mild	2 (2.5%)	2 (2.9%)	1 (1.1%)	(0.0%)	5 (1.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
MIGRAINE HEADACHES	-Total-	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
PARAESTHESIAS AND DYSAESTHESIAS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
MONONEUROPATHIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SENSORY ABNORMALITIES NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SPINAL CORD AND NERVE ROOT DISORDERS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
PSYCHIATRIC DISORDERS						
- Overall -	-Total-	2 (2.5%)	1 (1.4%)	5 (5.7%)	1 (1.2%)	9 (2.8%)
	Mild	2 (2.5%)	(0.0%)	4 (4.6%)	(0.0%)	6 (1.9%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ANXIETY SYMPTOMS	-Total-	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
AFFECT ALTERATIONS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INCREASED PHYSICAL ACTIVITY LEVELS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDERS AND SYMPTOMS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PANIC ATTACKS AND DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SLEEP DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RENAL AND URINARY DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
URINARY ABNORMALITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
- Overall -	-Total-	3 (3.8%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	8 (2.5%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Moderate	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVIX DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BENIGN AND MALIGNANT BREAST NEOPLASMS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MENSTRUATION AND UTERINE BLEEDING NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MENSTRUATION WITH INCREASED BLEEDING	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
REPRODUCTIVE TRACT SIGNS AND SYMPTOMS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VULVOVAGINAL CYSTS AND NEOPLASMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS						
- Overall -	-Total-	10 (12.5%)	5 (7.1%)	12 (13.8%)	4 (4.9%)	31 (9.7%)
	Mild	5 (6.3%)	3 (4.3%)	10 (11.5%)	2 (2.5%)	20 (6.3%)
	Moderate	4 (5.0%)	2 (2.9%)	2 (2.3%)	2 (2.5%)	10 (3.1%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	-Total-	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
	Mild	2 (2.5%)	1 (1.4%)	5 (5.7%)	(0.0%)	8 (2.5%)
	Moderate	2 (2.5%)	1 (1.4%)	(0.0%)	(0.0%)	3 (0.9%)
NASAL CONGESTION AND INFLAMMATIONS	-Total-	2 (2.5%)	2 (2.9%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
	Mild	2 (2.5%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
BRONCHOSPASM AND OBSTRUCTION	-Total-	3 (3.8%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	8 (2.5%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS						
COUGHING AND ASSOCIATED SYMPTOMS	-Total-	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
	Mild	1 (1.3%)	2 (2.9%)	2 (2.3%)	(0.0%)	5 (1.6%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
- Overall -	-Total-	13 (16.3%)	13 (18.6%)	10 (11.5%)	9 (11.1%)	45 (14.2%)
	Mild	5 (6.3%)	5 (7.1%)	5 (5.7%)	2 (2.5%)	17 (5.3%)
	Moderate	6 (7.5%)	4 (5.7%)	3 (3.4%)	6 (7.4%)	19 (6.0%)
	Severe	2 (2.5%)	4 (5.7%)	2 (2.3%)	1 (1.2%)	9 (2.8%)
URTICARIAS	-Total-	8 (10.0%)	9 (12.9%)	5 (5.7%)	3 (3.7%)	25 (7.9%)
	Mild	1 (1.3%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	6 (1.9%)
	Moderate	5 (6.3%)	3 (4.3%)	2 (2.3%)	2 (2.5%)	12 (3.8%)
	Severe	2 (2.5%)	4 (5.7%)	1 (1.1%)	(0.0%)	7 (2.2%)
ANGIOEDEMAS	-Total-	5 (6.3%)	(0.0%)	(0.0%)	3 (3.7%)	8 (2.5%)
	Mild	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	3 (3.8%)	(0.0%)	(0.0%)	2 (2.5%)	5 (1.6%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PRURITUS NEC	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class / High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
ALOPECIAS	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
DERMATITIS AND ECZEMA	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
APOCRINE AND ECCRINE GLAND DISORDERS	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DERMAL AND EPIDERMAL CONDITIONS NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RASHES, ERUPTIONS AND EXANTHEMS NEC	-Total-	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
EXFOLIATIVE CONDITIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NAIL AND NAIL BED CONDITIONS (EXCL INFECTIONS AND INFESTATIONS)	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PAPULOSQUAMOUS CONDITIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PURPURA AND RELATED CONDITIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/10
Patients with Treatment-Emergent Adverse Events Occurring During the Treatment Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SURGICAL AND MEDICAL PROCEDURES						
- Overall -	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
EYELID THERAPEUTIC PROCEDURES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
JOINT THERAPEUTIC PROCEDURES	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VASCULAR DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VASCULAR HYPERTENSIVE DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PERIPHERAL VASCULAR DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

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Table 14.3/6
Patients with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	7 (8.8%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	15 (4.7%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OEDEMA NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OEDEMA PERIPHERAL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DRUG HYPERSENSITIVITY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
ARTHRALGIA	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
JOINT EFFUSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
JOINT SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PAIN IN EXTREMITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HEADACHES NEC	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HEADACHE	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/6
Patients with Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
BRONCHOSPASM AND OBSTRUCTION	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ASTHMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	3 (3.8%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	8 (2.5%)
URTICARIAS	3 (3.8%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	8 (2.5%)
URTICARIA	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
IDIOPATHIC URTICARIA	2 (2.5%)	1 (1.4%)	(0.0%)	(0.0%)	3 (0.9%)
ANGIOEDEMAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGIOEDEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/7
Patients with Treatment-Emergent Adverse Events Leading to Death
Safety-Evaluable Patients

No observations

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/11
Patients with Treatment-Emergent Serious Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	4 (5.0%)	2 (2.9%)	3 (3.4%)	(0.0%)	9 (2.8%)
CARDIAC DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ISCHAEMIC CORONARY ARTERY DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGINA UNSTABLE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
APPENDICITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UPPER LIMB FRACTURES AND DISLOCATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RADIUS FRACTURE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent serious adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/11
Patients with Treatment-Emergent Serious Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
METABOLISM AND NUTRITION DISORDERS					
DIABETES MELLITUS (INCL SUBTYPES)	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TYPE 2 DIABETES MELLITUS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PAIN IN EXTREMITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVIX DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVICAL DYSPLASIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BRONCHOSPASM AND OBSTRUCTION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
URTICARIAS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
URTICARIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
VASCULAR DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent serious adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/11
Patients with Treatment-Emergent Serious Adverse Events Occurring During the Treatment Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
VASCULAR DISORDERS					
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERTENSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent serious adverse events that started on or after the first treatment date through treatment completion (Week 24) or treatment discontinuation.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/14
Patients with Treatment-Emergent Serious Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
IMMUNE SYSTEM DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC RESPONSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYPOGLYCAEMIC CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SHOCK HYPOGLYCAEMIC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
URTICARIAS	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
IDIOPATHIC URTICARIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
URTICARIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGIOEDEMAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGIOEDEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SURGICAL AND MEDICAL PROCEDURES					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABORTION INDUCED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent serious adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/1
Extent of Exposure to Study Drug
Safety-Evaluable Patients

	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Duration of Exposure (weeks)					
n	80	70	87	81	318
Mean (SD)	20.4 (6.9)	22.0 (5.3)	21.8 (5.1)	22.2 (5.2)	21.6 (5.7)
Median	24.0	24.0	24.0	24.0	24.0
Range	4 - 25	4 - 25	4 - 26	4 - 25	4 - 26
Duration of Exposure (weeks)					
n	80	70	87	81	318
1-4	7 (8.8%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	15 (4.7%)
5-8	6 (7.5%)	4 (5.7%)	6 (6.9%)	(0.0%)	16 (5.0%)
9-12	2 (2.5%)	1 (1.4%)	3 (3.4%)	3 (3.7%)	9 (2.8%)
13-16	2 (2.5%)	3 (4.3%)	3 (3.4%)	(0.0%)	8 (2.5%)
17-20	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
21-24	59 (73.8%)	58 (82.9%)	64 (73.6%)	71 (87.7%)	252 (79.2%)
>24	3 (3.8%)	2 (2.9%)	7 (8.0%)	2 (2.5%)	14 (4.4%)
Number of Doses					
n	80	70	87	81	318
Mean (SD)	5.1 (1.7)	5.5 (1.3)	5.4 (1.3)	5.6 (1.3)	5.4 (1.4)
Median	6.0	6.0	6.0	6.0	6.0
Range	1 - 6	1 - 6	1 - 6	1 - 6	1 - 6
Total Cumulative Dose (mg)					
n	0	70	87	81	238
Mean (SD)	NE (NE)	409.1 (98.6)	784.2 (204.4)	1666.7 (393.3)	974.2 (584.5)
Median	NE	450.0	900.0	1800.0	900.0
Range	NE - NE	75 - 450	150 - 913	300 - 1800	75 - 1800
Missed Doses					
n	80	70	87	81	318
0	60 (75.0%)	58 (82.9%)	69 (79.3%)	72 (88.9%)	259 (81.4%)

Duration of study drug exposure in weeks will be defined as the date of the last treatment visit minus the date of the first study drug administration + 1 + 4 weeks (28 days).
NE=Not evaluable

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eesd)
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Table 14.3/1
Extent of Exposure to Study Drug
Safety-Evaluable Patients

	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
1	3 (3.8%)	1 (1.4%)	5 (5.7%)	1 (1.2%)	10 (3.1%)
2	2 (2.5%)	4 (5.7%)	3 (3.4%)	(0.0%)	9 (2.8%)
3	2 (2.5%)	1 (1.4%)	3 (3.4%)	3 (3.7%)	9 (2.8%)
4	6 (7.5%)	4 (5.7%)	6 (6.9%)	(0.0%)	16 (5.0%)
5	7 (8.8%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	15 (4.7%)

Duration of study drug exposure in weeks will be defined as the date of the last treatment visit minus the date of the first study drug administration + 1 + 4 weeks (28 days).
NE=Not evaluable

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_eesd)
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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	53 (66.3%)	55 (78.6%)	72 (82.8%)	57 (70.4%)	237 (74.5%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
ANAEMIAS NEC	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ANAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HAEMORRHAGIC ANAEMIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOCYTOSES NEC	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
LEUKOCYTOSIS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
NEUTROPHILIA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANAEMIA DEFICIENCIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
IRON DEFICIENCY ANAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NEUTROPENIAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NEUTROPENIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THROMBOCYTOPENIAS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THROMBOCYTOPENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CARDIAC DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
RATE AND RHYTHM DISORDERS NEC	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ARRHYTHMIA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
BRADYCARDIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ISCHAEMIC CORONARY ARTERY DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGINA UNSTABLE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
CARDIAC DISORDERS					
MYOCARDIAL DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARDIOMEGALY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
CENTRAL NERVOUS SYSTEM DISORDERS CONGENITAL NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SYRINGOMYELIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
COAGULATION DISORDERS CONGENITAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FACTOR V DEFICIENCY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
INNER EAR SIGNS AND SYMPTOMS	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
VERTIGO	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
TINNITUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ENDOCRINE DISORDERS					
- Overall -	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
THYROID DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GOITRE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THYROID HYPOFUNCTION DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPOTHYROIDISM	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EYE DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	2 (2.3%)	3 (3.7%)	6 (1.9%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
EYE DISORDERS					
CONJUNCTIVAL INFECTIONS, IRRITATIONS AND INFLAMMATIONS	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
CONJUNCTIVITIS	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
LACRIMAL DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DRY EYE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OCULAR DISORDERS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EYE PAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VISUAL DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VISUAL IMPAIRMENT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS					
- Overall -	7 (8.8%)	12 (17.1%)	9 (10.3%)	8 (9.9%)	36 (11.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	1 (1.3%)	4 (5.7%)	2 (2.3%)	2 (2.5%)	9 (2.8%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	3 (4.3%)	2 (2.3%)	2 (2.5%)	7 (2.2%)
CONSTIPATION	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
ABDOMINAL PAIN UPPER	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
ABDOMINAL PAIN	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
ABDOMINAL PAIN LOWER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL PAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DENTAL PAIN AND SENSATION DISORDERS	(0.0%)	3 (4.3%)	2 (2.3%)	(0.0%)	5 (1.6%)
TOOTHACHE	(0.0%)	2 (2.9%)	2 (2.3%)	(0.0%)	4 (1.3%)
SENSITIVITY OF TEETH	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NAUSEA AND VOMITING SYMPTOMS	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
NAUSEA	1 (1.3%)	2 (2.9%)	(0.0%)	1 (1.2%)	4 (1.3%)
VOMITING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS					
GASTROINTESTINAL SIGNS AND SYMPTOMS NEC	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
ABDOMINAL DISCOMFORT	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
DIARRHOEA (EXCL INFECTIVE)	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
DIARRHOEA	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
GASTRITIS (EXCL INFECTIVE)	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
GASTRITIS	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
LIP SWELLING	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
DYSPEPTIC SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DYSPEPSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL HAEMORRHAGES	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL BLEEDING	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INTESTINAL HAEMORRHAGES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RECTAL HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NON-SITE SPECIFIC GASTROINTESTINAL HAEMORRHAGES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMATOCHEZIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE PAIN AND PARAESTHESIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ODYNOPHAGIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
STOMATITIS AND ULCERATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MOUTH ULCERATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONGUE SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TONGUE COATED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	4 (5.0%)	7 (10.0%)	8 (9.2%)	9 (11.1%)	28 (8.8%)
OEDEMA NEC	2 (2.5%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
OEDEMA PERIPHERAL	2 (2.5%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
GENERAL SIGNS AND SYMPTOMS NEC	1 (1.3%)	3 (4.3%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
INFLUENZA LIKE ILLNESS	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
DISEASE PROGRESSION	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
LOCAL SWELLING	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FEBRILE DISORDERS	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
PYREXIA	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
INJECTION SITE REACTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	3 (3.7%)	5 (1.6%)
INJECTION SITE HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE PAIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJECTION SITE PRURITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE URTICARIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ASTHENIC CONDITIONS	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
FATIGUE	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ASTHENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PAIN AND DISCOMFORT NEC	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
CHEST DISCOMFORT	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
CHEST PAIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MASS CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CYST	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THERAPEUTIC AND NONTHERAPEUTIC RESPONSES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ADVERSE DRUG REACTION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/3
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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
IMMUNE SYSTEM DISORDERS					
- Overall -	2 (2.5%)	2 (2.9%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	2 (2.5%)	2 (2.9%)	(0.0%)	1 (1.2%)	5 (1.6%)
FOOD ALLERGY	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
DRUG HYPERSENSITIVITY	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ALLERGIC CONDITIONS NEC	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HYPERSENSITIVITY	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
ANAPHYLACTIC RESPONSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	32 (40.0%)	29 (41.4%)	43 (49.4%)	26 (32.1%)	130 (40.9%)
UPPER RESPIRATORY TRACT INFECTIONS	23 (28.8%)	19 (27.1%)	25 (28.7%)	19 (23.5%)	86 (27.0%)
NASOPHARYNGITIS	16 (20.0%)	5 (7.1%)	14 (16.1%)	10 (12.3%)	45 (14.2%)
SINUSITIS	5 (6.3%)	6 (8.6%)	7 (8.0%)	5 (6.2%)	23 (7.2%)
UPPER RESPIRATORY TRACT INFECTION	3 (3.8%)	6 (8.6%)	4 (4.6%)	4 (4.9%)	17 (5.3%)
PHARYNGITIS	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
ACUTE SINUSITIS	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
RHINITIS	2 (2.5%)	1 (1.4%)	(0.0%)	(0.0%)	3 (0.9%)
TONSILLITIS	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
CHRONIC SINUSITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	6 (7.5%)	5 (7.1%)	6 (6.9%)	2 (2.5%)	19 (6.0%)
BRONCHITIS	6 (7.5%)	5 (7.1%)	2 (2.3%)	2 (2.5%)	15 (4.7%)
LOWER RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
ATYPICAL PNEUMONIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PNEUMONIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
URINARY TRACT INFECTIONS	3 (3.8%)	3 (4.3%)	7 (8.0%)	3 (3.7%)	16 (5.0%)
URINARY TRACT INFECTION	3 (3.8%)	3 (4.3%)	7 (8.0%)	2 (2.5%)	15 (4.7%)
CYSTITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VIRAL INFECTIONS NEC	2 (2.5%)	4 (5.7%)	4 (4.6%)	2 (2.5%)	12 (3.8%)
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
BRONCHITIS VIRAL	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
GASTROENTERITIS VIRAL	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
GASTROINTESTINAL VIRAL INFECTION	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
VIRAL INFECTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EAR INFECTIONS	4 (5.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	6 (1.9%)
EAR INFECTION	3 (3.8%)	(0.0%)	(0.0%)	1 (1.2%)	4 (1.3%)
OTITIS MEDIA	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
BACTERIAL INFECTIONS NEC	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
CELLULITIS	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
FOLLICULITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PNEUMONIA BACTERIAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VAGINITIS BACTERIAL	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FUNGAL INFECTIONS NEC	1 (1.3%)	(0.0%)	4 (4.6%)	(0.0%)	5 (1.6%)
FUNGAL INFECTION	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
ONYCHOMYCOSIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STREPTOCOCCAL INFECTIONS	2 (2.5%)	(0.0%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
PHARYNGITIS STREPTOCOCCAL	2 (2.5%)	(0.0%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
TOOTH INFECTION	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
TOOTH ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Database (CLOSED) Datasets (dae pat)
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Table 14.3/3
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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
HERPES VIRAL INFECTIONS	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
ORAL HERPES	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
HERPES ZOSTER	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN STRUCTURES AND SOFT TISSUE INFECTIONS	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
SKIN INFECTION	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
FURUNCLE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SUBCUTANEOUS ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
APPENDICITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROENTERITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CANDIDA INFECTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
CANDIDIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL CANDIDIASIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INFECTIONS NEC	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
INFLUENZA VIRAL INFECTIONS	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
INFLUENZA	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
BREAST INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BREAST ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MYCOPLASMA INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PNEUMONIA MYCOPLASMAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL SKIN INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Table 14.3/3
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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
TINEA INFECTIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BODY TINEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
- Overall -	4 (5.0%)	4 (5.7%)	1 (1.1%)	8 (9.9%)	17 (5.3%)
NON-SITE SPECIFIC INJURIES NEC	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
FALL	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ANIMAL BITE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
POST CONCUSSION SYNDROME	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LIMB INJURIES NEC (INCL TRAUMATIC AMPUTATION)	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
MENISCUS LESION	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
JOINT INJURY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LIMB INJURY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LOWER LIMB FRACTURES AND DISLOCATIONS	(0.0%)	(0.0%)	(0.0%)	3 (3.7%)	3 (0.9%)
FOOT FRACTURE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
ANKLE FRACTURE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN INJURIES NEC	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
CONTUSION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EXCORIATION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN INJURY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE, TENDON AND LIGAMENT INJURIES	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
LIGAMENT SPRAIN	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
CEREBRAL INJURIES NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CONCUSSION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PERIPHERAL NERVE INJURIES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MEDIAN NERVE INJURY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
SITE SPECIFIC INJURIES NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TOOTH FRACTURE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THORACIC CAGE FRACTURES AND DISLOCATIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
RIB FRACTURE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
UPPER LIMB FRACTURES AND DISLOCATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RADIUS FRACTURE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INVESTIGATIONS					
- Overall -	3 (3.8%)	2 (2.9%)	4 (4.6%)	5 (6.2%)	14 (4.4%)
PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
WEIGHT DECREASED	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
WEIGHT INCREASED	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
VASCULAR TESTS NEC (INCL BLOOD PRESSURE)	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
BLOOD PRESSURE INCREASED	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
BLOOD PRESSURE SYSTOLIC INCREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
SERUM FERRITIN DECREASED	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
CARBOHYDRATE TOLERANCE ANALYSES (INCL DIABETES)	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BLOOD GLUCOSE INCREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CHOLESTEROL ANALYSES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BLOOD CHOLESTEROL INCREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HEART RATE AND PULSE INVESTIGATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HEART RATE INCREASED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INVESTIGATIONS					
RED BLOOD CELL ANALYSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HAEMOGLOBIN DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
WHITE BLOOD CELL ANALYSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
WHITE BLOOD CELL COUNT DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
DIABETES MELLITUS (INCL SUBTYPES)	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DIABETES MELLITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TYPE 2 DIABETES MELLITUS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
APPETITE DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DECREASED APPETITE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ELEVATED TRIGLYCERIDES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERTRIGLYCERIDAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FLUID INTAKE INCREASED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
POLYDIPSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIC CONDITIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERLIPIDAEMIAS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERLIPIDAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPOGLYCAEMIC CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SHOCK HYPOGLYCAEMIC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	4 (5.0%)	9 (12.9%)	14 (16.1%)	12 (14.8%)	39 (12.3%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	4 (5.7%)	6 (6.9%)	5 (6.2%)	15 (4.7%)
ARTHRALGIA	(0.0%)	3 (4.3%)	5 (5.7%)	4 (4.9%)	12 (3.8%)
JOINT SWELLING	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
JOINT EFFUSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	3 (3.8%)	3 (4.3%)	5 (5.7%)	4 (4.9%)	15 (4.7%)
BACK PAIN	3 (3.8%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
PAIN IN EXTREMITY	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
MUSCULOSKELETAL PAIN	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
NECK PAIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE PAINS	(0.0%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
MYALGIA	(0.0%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
MUSCLE SPASMS	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
BONE RELATED SIGNS AND SYMPTOMS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
COCCYDYNIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSAL DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EXTREMITY DEFORMITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FOOT DEFORMITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC PROTRUSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE WEAKNESS CONDITIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULAR WEAKNESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Safety-Evaluable Patients

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MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
MUSCULOSKELETAL AND CONNECTIVE TISSUE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFLAMMATIONS NEC					
PLANTAR FASCIITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OSTEOARTHROPATHIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
OSTEOARTHRITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TENDON DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TENDONITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)					
- Overall -	2 (2.5%)	3 (4.3%)	(0.0%)	1 (1.2%)	6 (1.9%)
BONE NEOPLASMS BENIGN (EXCL CYSTS)	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMANGIOMA OF BONE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
BREAST AND NIPPLE NEOPLASMS BENIGN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LIPOMA OF BREAST	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ENDOCRINE NEOPLASMS BENIGN NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PARATHYROID TUMOUR BENIGN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEUROMAS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NEUROMA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN NEOPLASMS BENIGN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN PAPILLOMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE NEOPLASMS BENIGN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE LEIOMYOMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS					
- Overall -	7 (8.8%)	11 (15.7%)	18 (20.7%)	10 (12.3%)	46 (14.5%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Database (CLOSED) Datasets (dae pat)
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Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NERVOUS SYSTEM DISORDERS					
HEADACHES NEC	3 (3.8%)	5 (7.1%)	14 (16.1%)	7 (8.6%)	29 (9.1%)
HEADACHE	3 (3.8%)	5 (7.1%)	12 (13.8%)	7 (8.6%)	27 (8.5%)
SINUS HEADACHE	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	2 (2.5%)	3 (4.3%)	2 (2.3%)	1 (1.2%)	8 (2.5%)
DIZZINESS	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
PRESYNCOPE	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
MIGRAINE HEADACHES	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
MIGRAINE	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
SENSORY ABNORMALITIES NEC	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
HYPOAESTHESIA	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
HYPOGEUSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PARAESTHESIAS AND DYSAESTHESIAS	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
HYPERAESTHESIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PARAESTHESIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MONONEUROPATHIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARPAL TUNNEL SYNDROME	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NARCOLEPSY AND HYPERSOMNIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERSOMNIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OLFACTORY NERVE DISORDERS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPOSMIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SPINAL CORD AND NERVE ROOT DISORDERS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NERVE ROOT LESION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PSYCHIATRIC DISORDERS					
- Overall -	2 (2.5%)	2 (2.9%)	7 (8.0%)	1 (1.2%)	12 (3.8%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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PSYCHIATRIC DISORDERS					
ANXIETY SYMPTOMS	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
ANXIETY	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
INSOMNIA	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
AFFECT ALTERATIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
AFFECT LABILITY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EMOTIONAL AND MOOD DISTURBANCES NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EMOTIONAL DISTRESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INCREASED PHYSICAL ACTIVITY LEVELS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESTLESSNESS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDERS AND SYMPTOMS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PANIC ATTACKS AND DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PANIC ATTACK	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SEXUAL DESIRE DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LIBIDO DECREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SLEEP DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SLEEP DISORDER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RENAL AND URINARY DISORDERS					
- Overall -	2 (2.5%)	(0.0%)	2 (2.3%)	(0.0%)	4 (1.3%)
RENAL LITHIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEPHROLITHIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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RENAL AND URINARY DISORDERS					
URINARY ABNORMALITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LEUKOCYTURIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT LITHIASIS (EXCL RENAL)	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CALCULUS URINARY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT SIGNS AND SYMPTOMS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
POLYURIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
- Overall -	5 (6.3%)	1 (1.4%)	4 (4.6%)	3 (3.7%)	13 (4.1%)
CERVIX DISORDERS NEC	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
CERVICAL DYSPLASIA	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
MENSTRUATION WITH INCREASED BLEEDING	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
MENORRHAGIA	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
OVARIAN AND FALLOPIAN TUBE CYSTS AND NEOPLASMS	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
OVARIAN CYST	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
POLYCYSTIC OVARIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BENIGN AND MALIGNANT BREAST NEOPLASMS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
BREAST CYST	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MENSTRUATION AND UTERINE BLEEDING NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DYSMENORRHOEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROSTATIC SIGNS, SYMPTOMS AND DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROSTATOMEGALY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE TRACT SIGNS AND SYMPTOMS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PELVIC PAIN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
UTERINE DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UTERINE ENLARGEMENT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VULVOVAGINAL CYSTS AND NEOPLASMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VAGINAL CYST	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	14 (17.5%)	7 (10.0%)	18 (20.7%)	5 (6.2%)	44 (13.8%)
BRONCHOSPASM AND OBSTRUCTION	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
ASTHMA	4 (5.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	11 (3.5%)
WHEEZING	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NASAL CONGESTION AND INFLAMMATIONS	3 (3.8%)	2 (2.9%)	4 (4.6%)	3 (3.7%)	12 (3.8%)
NASAL CONGESTION	3 (3.8%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	8 (2.5%)
RHINITIS ALLERGIC	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	5 (6.3%)	2 (2.9%)	5 (5.7%)	(0.0%)	12 (3.8%)
OROPHARYNGEAL PAIN	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
RHINORRHOEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
COUGHING AND ASSOCIATED SYMPTOMS	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
COUGH	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
SINUS CONGESTION	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
PARANASAL SINUS HYPERSECRETION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BREATHING ABNORMALITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DYSPNOEA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
PHARYNGEAL DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONSILLOLITH	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	20 (25.0%)	25 (35.7%)	19 (21.8%)	25 (30.9%)	89 (28.0%)
URTICARIAS	13 (16.3%)	17 (24.3%)	14 (16.1%)	16 (19.8%)	60 (18.9%)
IDIOPATHIC URTICARIA	5 (6.3%)	10 (14.3%)	6 (6.9%)	11 (13.6%)	32 (10.1%)
URTICARIA	8 (10.0%)	9 (12.9%)	8 (9.2%)	5 (6.2%)	30 (9.4%)
ANGIOEDEMAS	5 (6.3%)	1 (1.4%)	3 (3.4%)	4 (4.9%)	13 (4.1%)
ANGIOEDEMA	3 (3.8%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
SWELLING FACE	2 (2.5%)	(0.0%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
PRURITUS NEC	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
PRURITUS	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
ALOPECIAS	(0.0%)	2 (2.9%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
ALOPECIA	(0.0%)	2 (2.9%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
MADAROSIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DERMATITIS AND ECZEMA	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
DERMATITIS	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
ECZEMA	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DERMATITIS CONTACT	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
APOCRINE AND ECCRINE GLAND DISORDERS	2 (2.5%)	1 (1.4%)	(0.0%)	1 (1.2%)	4 (1.3%)
NIGHT SWEATS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HIDRADENITIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERHIDROSIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
RASHES, ERUPTIONS AND EXANTHEMS NEC	2 (2.5%)	2 (2.9%)	(0.0%)	(0.0%)	4 (1.3%)
RASH	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
RASH MACULO-PAPULAR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ERYTHEMAS	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
ERYTHEMA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
RASH ERYTHEMATOUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DERMAL AND EPIDERMAL CONDITIONS NEC	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DRY SKIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PAIN OF SKIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PURPURA AND RELATED CONDITIONS	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
ECCHYMOSIS	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
EXFOLIATIVE CONDITIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN EXFOLIATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NAIL AND NAIL BED CONDITIONS (EXCL INFECTIONS AND INFESTATIONS)	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NAIL DYSTROPHY	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PAPULOSQUAMOUS CONDITIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ERYTHEMA ANNULARE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PHOTOSENSITIVITY CONDITIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SUNBURN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SURGICAL AND MEDICAL PROCEDURES					
- Overall -	1 (1.3%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	7 (2.2%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/3
Patients with Treatment-Emergent Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SURGICAL AND MEDICAL PROCEDURES					
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
DENTAL OPERATION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
TOOTH EXTRACTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TOOTH REPAIR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
JOINT THERAPEUTIC PROCEDURES	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
JOINT SURGERY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
KNEE OPERATION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EYELID THERAPEUTIC PROCEDURES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
EYELID OPERATION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABORTION INDUCED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN LESION EXCISIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MOLE EXCISION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VASCULAR DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
HYPERTENSION	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
PERIPHERAL VASCULAR DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HOT FLUSH	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	-Total-	53 (66.3%)	55 (78.6%)	72 (82.8%)	57 (70.4%)	237 (74.5%)
	Mild	23 (28.8%)	21 (30.0%)	31 (35.6%)	18 (22.2%)	93 (29.2%)
	Moderate	22 (27.5%)	27 (38.6%)	33 (37.9%)	26 (32.1%)	108 (34.0%)
	Severe	8 (10.0%)	7 (10.0%)	8 (9.2%)	13 (16.0%)	36 (11.3%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Moderate	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
ANAEMIAS NEC	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
LEUKOCYTOSES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANAEMIA DEFICIENCIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NEUTROPENIAS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THROMBOCYTOPENIAS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
CARDIAC DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RATE AND RHYTHM DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ISCHAEMIC CORONARY ARTERY DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MYOCARDIAL DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS						
- Overall -	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
CENTRAL NERVOUS SYSTEM DISORDERS CONGENITAL NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
COAGULATION DISORDERS CONGENITAL	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
EAR AND LABYRINTH DISORDERS						
INNER EAR SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
ENDOCRINE DISORDERS						
- Overall -	-Total-	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
THYROID DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THYROID HYPOFUNCTION DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EYE DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	3 (3.7%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
CONJUNCTIVAL INFECTIONS, IRRITATIONS AND INFLAMMATIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
LACRIMAL DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OCULAR DISORDERS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
EYE DISORDERS						
VISUAL DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS						
- Overall -	-Total-	7 (8.8%)	12 (17.1%)	9 (10.3%)	8 (9.9%)	36 (11.3%)
	Mild	6 (7.5%)	9 (12.9%)	6 (6.9%)	6 (7.4%)	27 (8.5%)
	Moderate	1 (1.3%)	3 (4.3%)	2 (2.3%)	2 (2.5%)	8 (2.5%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	-Total-	1 (1.3%)	4 (5.7%)	2 (2.3%)	2 (2.5%)	9 (2.8%)
	Mild	1 (1.3%)	4 (5.7%)	(0.0%)	2 (2.5%)	7 (2.2%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
	Mild	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DENTAL PAIN AND SENSATION DISORDERS	-Total-	(0.0%)	3 (4.3%)	2 (2.3%)	(0.0%)	5 (1.6%)
	Mild	(0.0%)	2 (2.9%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NAUSEA AND VOMITING SYMPTOMS	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS						
GASTROINTESTINAL SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DIARRHOEA (EXCL INFECTIVE)	-Total-	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
GASTRITIS (EXCL INFECTIVE)	-Total-	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
DYSPEPTIC SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL HAEMORRHAGES	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INTESTINAL HAEMORRHAGES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NON-SITE SPECIFIC GASTROINTESTINAL HAEMORRHAGES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE PAIN AND PARAESTHESIA	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS						
STOMATITIS AND ULCERATION	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONGUE SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
- Overall -	-Total-	4 (5.0%)	7 (10.0%)	8 (9.2%)	9 (11.1%)	28 (8.8%)
	Mild	3 (3.8%)	3 (4.3%)	4 (4.6%)	3 (3.7%)	13 (4.1%)
	Moderate	1 (1.3%)	3 (4.3%)	4 (4.6%)	6 (7.4%)	14 (4.4%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
OEDEMA NEC	-Total-	2 (2.5%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
GENERAL SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	3 (4.3%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
FEBRILE DISORDERS	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE REACTIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	3 (3.7%)	5 (1.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
ASTHENIC CONDITIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PAIN AND DISCOMFORT NEC	-Total-	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MASS CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THERAPEUTIC AND NONTHERAPEUTIC RESPONSES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS						
- Overall -	-Total-	2 (2.5%)	2 (2.9%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	-Total-	2 (2.5%)	2 (2.9%)	(0.0%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ALLERGIC CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
IMMUNE SYSTEM DISORDERS						
ANAPHYLACTIC RESPONSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFESTATIONS						
- Overall -	-Total-	32 (40.0%)	29 (41.4%)	43 (49.4%)	26 (32.1%)	130 (40.9%)
	Mild	21 (26.3%)	19 (27.1%)	27 (31.0%)	18 (22.2%)	85 (26.7%)
	Moderate	11 (13.8%)	10 (14.3%)	15 (17.2%)	8 (9.9%)	44 (13.8%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UPPER RESPIRATORY TRACT INFECTIONS	-Total-	23 (28.8%)	19 (27.1%)	25 (28.7%)	19 (23.5%)	86 (27.0%)
	Mild	18 (22.5%)	16 (22.9%)	17 (19.5%)	14 (17.3%)	65 (20.4%)
	Moderate	5 (6.3%)	3 (4.3%)	8 (9.2%)	5 (6.2%)	21 (6.6%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	-Total-	6 (7.5%)	5 (7.1%)	6 (6.9%)	2 (2.5%)	19 (6.0%)
	Mild	4 (5.0%)	1 (1.4%)	4 (4.6%)	(0.0%)	9 (2.8%)
	Moderate	2 (2.5%)	4 (5.7%)	2 (2.3%)	2 (2.5%)	10 (3.1%)
URINARY TRACT INFECTIONS	-Total-	3 (3.8%)	3 (4.3%)	7 (8.0%)	3 (3.7%)	16 (5.0%)
	Mild	2 (2.5%)	2 (2.9%)	4 (4.6%)	2 (2.5%)	10 (3.1%)
	Moderate	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
VIRAL INFECTIONS NEC	-Total-	2 (2.5%)	4 (5.7%)	4 (4.6%)	2 (2.5%)	12 (3.8%)
	Mild	2 (2.5%)	2 (2.9%)	3 (3.4%)	2 (2.5%)	9 (2.8%)
	Moderate	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
EAR INFECTIONS	-Total-	4 (5.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Moderate	4 (5.0%)	(0.0%)	(0.0%)	(0.0%)	4 (1.3%)

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
BACTERIAL INFECTIONS NEC	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FUNGAL INFECTIONS NEC	-Total-	1 (1.3%)	(0.0%)	4 (4.6%)	(0.0%)	5 (1.6%)
	Mild	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STREPTOCOCCAL INFECTIONS	-Total-	2 (2.5%)	(0.0%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
	Mild	2 (2.5%)	(0.0%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
HERPES VIRAL INFECTIONS	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN STRUCTURES AND SOFT TISSUE INFECTIONS	-Total-	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
CANDIDA INFECTIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
INFECTIONS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFLUENZA VIRAL INFECTIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
BREAST INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MYCOPLASMA INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TINEA INFECTIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
- Overall -	-Total-	4 (5.0%)	4 (5.7%)	1 (1.1%)	8 (9.9%)	17 (5.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	3 (3.7%)	4 (1.3%)
	Moderate	2 (2.5%)	3 (4.3%)	1 (1.1%)	5 (6.2%)	11 (3.5%)
	Severe	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)

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Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
NON-SITE SPECIFIC INJURIES NEC	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
LIMB INJURIES NEC (INCL TRAUMATIC AMPUTATION)	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	2 (2.5%)	4 (1.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
LOWER LIMB FRACTURES AND DISLOCATIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	3 (3.7%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
SKIN INJURIES NEC	-Total-	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
MUSCLE, TENDON AND LIGAMENT INJURIES	-Total-	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
CEREBRAL INJURIES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PERIPHERAL NERVE INJURIES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SITE SPECIFIC INJURIES NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THORACIC CAGE FRACTURES AND DISLOCATIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
UPPER LIMB FRACTURES AND DISLOCATIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INVESTIGATIONS						
- Overall -	-Total-	3 (3.8%)	2 (2.9%)	4 (4.6%)	5 (6.2%)	14 (4.4%)
	Mild	3 (3.8%)	2 (2.9%)	4 (4.6%)	3 (3.7%)	12 (3.8%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
PHYSICAL EXAMINATION PROCEDURES AND ORGAN SYSTEM STATUS	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
VASCULAR TESTS NEC (INCL BLOOD PRESSURE)	-Total-	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
CARBOHYDRATE TOLERANCE ANALYSES (INCL DIABETES)	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CHOLESTEROL ANALYSES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HEART RATE AND PULSE INVESTIGATIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INVESTIGATIONS						
RED BLOOD CELL ANALYSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
WHITE BLOOD CELL ANALYSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
DIABETES MELLITUS (INCL SUBTYPES)	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
APPETITE DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ELEVATED TRIGLYCERIDES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FLUID INTAKE INCREASED	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERGLYCAEMIC CONDITIONS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
METABOLISM AND NUTRITION DISORDERS						
HYPERLIPIDAEMIAS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPOGLYCAEMIC CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
- Overall -	-Total-	4 (5.0%)	9 (12.9%)	14 (16.1%)	12 (14.8%)	39 (12.3%)
	Mild	1 (1.3%)	6 (8.6%)	3 (3.4%)	4 (4.9%)	14 (4.4%)
	Moderate	2 (2.5%)	2 (2.9%)	8 (9.2%)	7 (8.6%)	19 (6.0%)
	Severe	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
JOINT RELATED SIGNS AND SYMPTOMS	-Total-	(0.0%)	4 (5.7%)	6 (6.9%)	5 (6.2%)	15 (4.7%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	4 (4.6%)	3 (3.7%)	8 (2.5%)
	Severe	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	-Total-	3 (3.8%)	3 (4.3%)	5 (5.7%)	4 (4.9%)	15 (4.7%)
	Mild	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
	Moderate	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
MUSCLE PAINS	-Total-	(0.0%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
BONE RELATED SIGNS AND SYMPTOMS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BURSAL DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EXTREMITY DEFORMITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INTERVERTEBRAL DISC DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE WEAKNESS CONDITIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE INFECTIONS AND INFLAMMATIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OSTEOARTHROPATHIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TENDON DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)						
- Overall -	-Total-	2 (2.5%)	3 (4.3%)	(0.0%)	1 (1.2%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	2 (2.5%)	2 (2.9%)	(0.0%)	1 (1.2%)	5 (1.6%)
BONE NEOPLASMS BENIGN (EXCL CYSTS)	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
BREAST AND NIPPLE NEOPLASMS BENIGN	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ENDOCRINE NEOPLASMS BENIGN NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEUROMAS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN NEOPLASMS BENIGN	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE NEOPLASMS BENIGN	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS						
- Overall -	-Total-	7 (8.8%)	11 (15.7%)	18 (20.7%)	10 (12.3%)	46 (14.5%)
	Mild	5 (6.3%)	9 (12.9%)	13 (14.9%)	7 (8.6%)	34 (10.7%)
	Moderate	1 (1.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	10 (3.1%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)

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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NERVOUS SYSTEM DISORDERS						
HEADACHES NEC	-Total-	3 (3.8%)	5 (7.1%)	14 (16.1%)	7 (8.6%)	29 (9.1%)
	Mild	1 (1.3%)	5 (7.1%)	11 (12.6%)	5 (6.2%)	22 (6.9%)
	Moderate	1 (1.3%)	(0.0%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	-Total-	2 (2.5%)	3 (4.3%)	2 (2.3%)	1 (1.2%)	8 (2.5%)
	Mild	2 (2.5%)	2 (2.9%)	1 (1.1%)	(0.0%)	5 (1.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
MIGRAINE HEADACHES	-Total-	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
	Mild	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
SENSORY ABNORMALITIES NEC	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
PARAESTHESIAS AND DYSAESTHESIAS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
MONONEUROPATHIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NARCOLEPSY AND HYPERSOMNIA	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OLFACTORY NERVE DISORDERS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SPINAL CORD AND NERVE ROOT DISORDERS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

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PSYCHIATRIC DISORDERS						
- Overall -	-Total-	2 (2.5%)	2 (2.9%)	7 (8.0%)	1 (1.2%)	12 (3.8%)
	Mild	2 (2.5%)	1 (1.4%)	6 (6.9%)	(0.0%)	9 (2.8%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
ANXIETY SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	-Total-	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
AFFECT ALTERATIONS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EMOTIONAL AND MOOD DISTURBANCES NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INCREASED PHYSICAL ACTIVITY LEVELS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
OBSESSIVE-COMPULSIVE DISORDERS AND SYMPTOMS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PANIC ATTACKS AND DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SEXUAL DESIRE DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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PSYCHIATRIC DISORDERS						
SLEEP DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RENAL AND URINARY DISORDERS						
- Overall -	-Total-	2 (2.5%)	(0.0%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RENAL LITHIASIS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
URINARY ABNORMALITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT LITHIASIS (EXCL RENAL)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
- Overall -	-Total-	5 (6.3%)	1 (1.4%)	4 (4.6%)	3 (3.7%)	13 (4.1%)
	Mild	2 (2.5%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	7 (2.2%)
	Moderate	2 (2.5%)	(0.0%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVIX DISORDERS NEC	-Total-	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
MENSTRUATION WITH INCREASED BLEEDING	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
OVARIAN AND FALLOPIAN TUBE CYSTS AND NEOPLASMS	-Total-	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
BENIGN AND MALIGNANT BREAST NEOPLASMS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MENSTRUATION AND UTERINE BLEEDING NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROSTATIC SIGNS, SYMPTOMS AND DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
REPRODUCTIVE TRACT SIGNS AND SYMPTOMS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
UTERINE DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VULVOVAGINAL CYSTS AND NEOPLASMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS						
- Overall -	-Total-	14 (17.5%)	7 (10.0%)	18 (20.7%)	5 (6.2%)	44 (13.8%)
	Mild	7 (8.8%)	5 (7.1%)	12 (13.8%)	3 (3.7%)	27 (8.5%)
	Moderate	6 (7.5%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	15 (4.7%)
	Severe	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
BRONCHOSPASM AND OBSTRUCTION	-Total-	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
	Mild	1 (1.3%)	2 (2.9%)	2 (2.3%)	2 (2.5%)	7 (2.2%)
	Moderate	3 (3.8%)	(0.0%)	2 (2.3%)	(0.0%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
NASAL CONGESTION AND INFLAMMATIONS	-Total-	3 (3.8%)	2 (2.9%)	4 (4.6%)	3 (3.7%)	12 (3.8%)
	Mild	3 (3.8%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
	Moderate	(0.0%)	1 (1.4%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	-Total-	5 (6.3%)	2 (2.9%)	5 (5.7%)	(0.0%)	12 (3.8%)
	Mild	2 (2.5%)	1 (1.4%)	5 (5.7%)	(0.0%)	8 (2.5%)
	Moderate	3 (3.8%)	1 (1.4%)	(0.0%)	(0.0%)	4 (1.3%)
COUGHING AND ASSOCIATED SYMPTOMS	-Total-	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
	Mild	2 (2.5%)	3 (4.3%)	3 (3.4%)	(0.0%)	8 (2.5%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
BREATHING ABNORMALITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PHARYNGEAL DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
- Overall -	-Total-	20 (25.0%)	25 (35.7%)	19 (21.8%)	25 (30.9%)	89 (28.0%)
	Mild	8 (10.0%)	7 (10.0%)	3 (3.4%)	6 (7.4%)	24 (7.5%)
	Moderate	10 (12.5%)	13 (18.6%)	11 (12.6%)	11 (13.6%)	45 (14.2%)
	Severe	2 (2.5%)	5 (7.1%)	5 (5.7%)	8 (9.9%)	20 (6.3%)
URTICARIAS	-Total-	13 (16.3%)	17 (24.3%)	14 (16.1%)	16 (19.8%)	60 (18.9%)
	Mild	2 (2.5%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	8 (2.5%)
	Moderate	9 (11.3%)	9 (12.9%)	9 (10.3%)	7 (8.6%)	34 (10.7%)
	Severe	2 (2.5%)	5 (7.1%)	4 (4.6%)	7 (8.6%)	18 (5.7%)
ANGIOEDEMAS	-Total-	5 (6.3%)	1 (1.4%)	3 (3.4%)	4 (4.9%)	13 (4.1%)
	Mild	2 (2.5%)	(0.0%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	3 (3.8%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
PRURITUS NEC	-Total-	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	2 (2.5%)	4 (1.3%)
	Moderate	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ALOPECIAS	-Total-	(0.0%)	2 (2.9%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
DERMATITIS AND ECZEMA	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
APOCRINE AND ECCRINE GLAND DISORDERS	-Total-	2 (2.5%)	1 (1.4%)	(0.0%)	1 (1.2%)	4 (1.3%)
	Mild	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
RASHES, ERUPTIONS AND EXANTHEMS NEC	-Total-	2 (2.5%)	2 (2.9%)	(0.0%)	(0.0%)	4 (1.3%)
	Mild	2 (2.5%)	2 (2.9%)	(0.0%)	(0.0%)	4 (1.3%)
ERYTHEMAS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
DERMAL AND EPIDERMAL CONDITIONS NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PURPURA AND RELATED CONDITIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
EXFOLIATIVE CONDITIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NAIL AND NAIL BED CONDITIONS (EXCL INFECTIONS AND INFESTATIONS)	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PAPULOSQUAMOUS CONDITIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
PHOTOSENSITIVITY CONDITIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SURGICAL AND MEDICAL PROCEDURES						
- Overall -	-Total-	1 (1.3%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	7 (2.2%)
	Mild	(0.0%)	2 (2.9%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
JOINT THERAPEUTIC PROCEDURES	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EYELID THERAPEUTIC PROCEDURES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN LESION EXCISIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VASCULAR DISORDERS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/4
Patients with Treatment-Emergent Adverse Events Occurring While On Study by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
VASCULAR DISORDERS						
VASCULAR HYPERTENSIVE DISORDERS NEC	-Total-	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PERIPHERAL VASCULAR DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/8.2
Treatment-Emergent Adverse Events Occurring During the Treatment Period with Incidence >=3% in Any Treatment Group
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	41 (51.3%)	41 (58.6%)	60 (69.0%)	46 (56.8%)	188 (59.1%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	2 (2.5%)	3 (4.3%)	7 (8.0%)	7 (8.6%)	19 (6.0%)
FEBRILE DISORDERS	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
PYREXIA	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
INFECTIONS AND INFESTATIONS					
- Overall -	22 (27.5%)	20 (28.6%)	32 (36.8%)	16 (19.8%)	90 (28.3%)
UPPER RESPIRATORY TRACT INFECTIONS	15 (18.8%)	12 (17.1%)	18 (20.7%)	13 (16.0%)	58 (18.2%)
NASOPHARYNGITIS	10 (12.5%)	3 (4.3%)	11 (12.6%)	9 (11.1%)	33 (10.4%)
SINUSITIS	4 (5.0%)	5 (7.1%)	4 (4.6%)	3 (3.7%)	16 (5.0%)
UPPER RESPIRATORY TRACT INFECTION	3 (3.8%)	3 (4.3%)	3 (3.4%)	1 (1.2%)	10 (3.1%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	5 (6.3%)	4 (5.7%)	4 (4.6%)	1 (1.2%)	14 (4.4%)
BRONCHITIS	5 (6.3%)	4 (5.7%)	2 (2.3%)	1 (1.2%)	12 (3.8%)
URINARY TRACT INFECTIONS	2 (2.5%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	9 (2.8%)
URINARY TRACT INFECTION	2 (2.5%)	1 (1.4%)	4 (4.6%)	1 (1.2%)	8 (2.5%)
FUNGAL INFECTIONS NEC	(0.0%)	(0.0%)	4 (4.6%)	(0.0%)	4 (1.3%)
FUNGAL INFECTION	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	2 (2.5%)	7 (10.0%)	12 (13.8%)	9 (11.1%)	30 (9.4%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	2 (2.5%)	3 (4.3%)	5 (5.7%)	2 (2.5%)	12 (3.8%)
PAIN IN EXTREMITY	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

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Table 14.3/8.2
Treatment-Emergent Adverse Events Occurring During the Treatment Period with Incidence >=3% in Any Treatment Group
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	2 (2.9%)	5 (5.7%)	4 (4.9%)	11 (3.5%)
ARTHRALGIA	(0.0%)	1 (1.4%)	5 (5.7%)	3 (3.7%)	9 (2.8%)
NERVOUS SYSTEM DISORDERS					
- Overall -	4 (5.0%)	7 (10.0%)	14 (16.1%)	8 (9.9%)	33 (10.4%)
HEADACHES NEC	2 (2.5%)	4 (5.7%)	10 (11.5%)	5 (6.2%)	21 (6.6%)
HEADACHE	2 (2.5%)	4 (5.7%)	8 (9.2%)	5 (6.2%)	19 (6.0%)
MIGRAINE HEADACHES	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
MIGRAINE	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	10 (12.5%)	5 (7.1%)	12 (13.8%)	4 (4.9%)	31 (9.7%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
OROPHARYNGEAL PAIN	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
COUGHING AND ASSOCIATED SYMPTOMS	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
COUGH	2 (2.5%)	3 (4.3%)	2 (2.3%)	(0.0%)	7 (2.2%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	13 (16.3%)	13 (18.6%)	10 (11.5%)	9 (11.1%)	45 (14.2%)
URTICARIAS	8 (10.0%)	9 (12.9%)	5 (5.7%)	3 (3.7%)	25 (7.9%)
URTICARIA	6 (7.5%)	5 (7.1%)	4 (4.6%)	2 (2.5%)	17 (5.3%)
IDIOPATHIC URTICARIA	2 (2.5%)	5 (7.1%)	1 (1.1%)	1 (1.2%)	9 (2.8%)
ANGIOEDEMAS	5 (6.3%)	(0.0%)	(0.0%)	3 (3.7%)	8 (2.5%)
ANGIOEDEMA	3 (3.8%)	(0.0%)	(0.0%)	3 (3.7%)	6 (1.9%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	32 (40.0%)	36 (51.4%)	45 (51.7%)	38 (46.9%)	151 (47.5%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
ANAEMIAS NEC	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ANAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HAEMORRHAGIC ANAEMIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LEUKOCYTOSES NEC	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
LEUKOCYTOSIS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
NEUTROPHILIA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANAEMIA DEFICIENCIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
IRON DEFICIENCY ANAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARDIAC DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MYOCARDIAL DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARDIOMEGALY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
INNER EAR SIGNS AND SYMPTOMS	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
VERTIGO	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ENDOCRINE DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
ENDOCRINE DISORDERS					
THYROID HYPOFUNCTION DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPOTHYROIDISM	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS					
- Overall -	2 (2.5%)	5 (7.1%)	4 (4.6%)	4 (4.9%)	15 (4.7%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
NAUSEA AND VOMITING SYMPTOMS	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
NAUSEA	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
VOMITING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DENTAL PAIN AND SENSATION DISORDERS	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
SENSITIVITY OF TEETH	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
TOOTHACHE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
ABDOMINAL PAIN UPPER	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
DYSPEPTIC SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DYSPEPSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GASTRITIS (EXCL INFECTIVE)	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GASTRITIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NON-SITE SPECIFIC GASTROINTESTINAL HAEMORRHAGES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMATOCHEZIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LIP SWELLING	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

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Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS					
STOMATITIS AND ULCERATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MOUTH ULCERATION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	2 (2.5%)	5 (7.1%)	1 (1.1%)	2 (2.5%)	10 (3.1%)
GENERAL SIGNS AND SYMPTOMS NEC	1 (1.3%)	3 (4.3%)	(0.0%)	1 (1.2%)	5 (1.6%)
DISEASE PROGRESSION	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
INFLUENZA LIKE ILLNESS	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
LOCAL SWELLING	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
OEDEMA NEC	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
OEDEMA PERIPHERAL	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
PAIN AND DISCOMFORT NEC	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
CHEST DISCOMFORT	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
ASTHENIC CONDITIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FATIGUE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THERAPEUTIC AND NONTHERAPEUTIC RESPONSES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ADVERSE DRUG REACTION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	3 (3.7%)	4 (1.3%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
DRUG HYPERSENSITIVITY	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
FOOD ALLERGY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALLERGIC CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYPERSENSITIVITY	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

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Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
IMMUNE SYSTEM DISORDERS					
ANAPHYLACTIC RESPONSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	15 (18.8%)	12 (17.1%)	22 (25.3%)	14 (17.3%)	63 (19.8%)
UPPER RESPIRATORY TRACT INFECTIONS	9 (11.3%)	8 (11.4%)	10 (11.5%)	9 (11.1%)	36 (11.3%)
NASOPHARYNGITIS	7 (8.8%)	2 (2.9%)	3 (3.4%)	2 (2.5%)	14 (4.4%)
SINUSITIS	1 (1.3%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	8 (2.5%)
UPPER RESPIRATORY TRACT INFECTION	(0.0%)	3 (4.3%)	2 (2.3%)	3 (3.7%)	8 (2.5%)
PHARYNGITIS	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
ACUTE SINUSITIS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
RHINITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
TONSILLITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
BRONCHITIS	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
LOWER RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
PNEUMONIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URINARY TRACT INFECTIONS	(0.0%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
URINARY TRACT INFECTION	(0.0%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
VIRAL INFECTIONS NEC	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
BRONCHITIS VIRAL	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
VIRAL UPPER RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
GASTROINTESTINAL VIRAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN STRUCTURES AND SOFT TISSUE INFECTIONS	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
SKIN INFECTION	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
FURUNCLE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SUBCUTANEOUS ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
BACTERIAL INFECTIONS NEC	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
CELLULITIS	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
FOLLICULITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
TOOTH INFECTION	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
TOOTH ABSCESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STREPTOCOCCAL INFECTIONS	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
PHARYNGITIS STREPTOCOCCAL	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
HERPES VIRAL INFECTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
ORAL HERPES	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
CANDIDA INFECTIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CANDIDIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EAR INFECTIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EAR INFECTION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FUNGAL INFECTIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FUNGAL INFECTION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INFLUENZA VIRAL INFECTIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFLUENZA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MYCOPLASMA INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PNEUMONIA MYCOPLASMAL	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TINEA INFECTIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BODY TINEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
- Overall -	2 (2.5%)	2 (2.9%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
NON-SITE SPECIFIC INJURIES NEC	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
FALL	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ANIMAL BITE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
POST CONCUSSION SYNDROME	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LOWER LIMB FRACTURES AND DISLOCATIONS	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
FOOT FRACTURE	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
SKIN INJURIES NEC	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
CONTUSION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EXCORIATION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CEREBRAL INJURIES NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CONCUSSION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE, TENDON AND LIGAMENT INJURIES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LIGAMENT SPRAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THORACIC CAGE FRACTURES AND DISLOCATIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
RIB FRACTURE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INVESTIGATIONS					
- Overall -	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
VASCULAR TESTS NEC (INCL BLOOD PRESSURE)	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
BLOOD PRESSURE INCREASED	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
BLOOD PRESSURE SYSTOLIC INCREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CHOLESTEROL ANALYSES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BLOOD CHOLESTEROL INCREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

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Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INVESTIGATIONS					
HEART RATE AND PULSE INVESTIGATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HEART RATE INCREASED	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SERUM FERRITIN DECREASED	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
WHITE BLOOD CELL ANALYSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
WHITE BLOOD CELL COUNT DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
APPETITE DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DECREASED APPETITE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYPOGLYCAEMIC CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SHOCK HYPOGLYCAEMIC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	3 (3.8%)	3 (4.3%)	5 (5.7%)	5 (6.2%)	16 (5.0%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	3 (4.3%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
ARTHRALGIA	(0.0%)	3 (4.3%)	2 (2.3%)	2 (2.5%)	7 (2.2%)
JOINT SWELLING	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
JOINT EFFUSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	2 (2.5%)	(0.0%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
BACK PAIN	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
PAIN IN EXTREMITY	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
NECK PAIN	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
EXTREMITY DEFORMITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
FOOT DEFORMITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE PAINS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MYALGIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE SPASMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TENDON DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
TENDONITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS					
- Overall -	3 (3.8%)	4 (5.7%)	4 (4.6%)	2 (2.5%)	13 (4.1%)
HEADACHES NEC	1 (1.3%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	8 (2.5%)
HEADACHE	1 (1.3%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	8 (2.5%)
SENSORY ABNORMALITIES NEC	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
HYPOAESTHESIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HYPOGEUSIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MIGRAINE HEADACHES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MIGRAINE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NARCOLEPSY AND HYPERSOMNIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPERSOMNIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PRESYNCOPE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
OLFACTORY NERVE DISORDERS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPOSMIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
PSYCHIATRIC DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
ANXIETY SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANXIETY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INSOMNIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
EMOTIONAL AND MOOD DISTURBANCES NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
EMOTIONAL DISTRESS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SEXUAL DESIRE DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LIBIDO DECREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RENAL AND URINARY DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
RENAL LITHIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEPHROLITHIASIS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
URINARY TRACT LITHIASIS (EXCL RENAL)	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CALCULUS URINARY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
- Overall -	2 (2.5%)	(0.0%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
OVARIAN AND FALLOPIAN TUBE CYSTS AND NEOPLASMS	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
OVARIAN CYST	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
POLYCYSTIC OVARIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CERVIX DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVICAL DYSPLASIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
MENSTRUATION WITH INCREASED BLEEDING	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MENORRHAGIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PROSTATIC SIGNS, SYMPTOMS AND DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PROSTATOMEGALY	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	6 (7.5%)	2 (2.9%)	7 (8.0%)	1 (1.2%)	16 (5.0%)
BRONCHOSPASM AND OBSTRUCTION	3 (3.8%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
ASTHMA	3 (3.8%)	(0.0%)	2 (2.3%)	1 (1.2%)	6 (1.9%)
WHEEZING	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NASAL CONGESTION AND INFLAMMATIONS	2 (2.5%)	(0.0%)	2 (2.3%)	(0.0%)	4 (1.3%)
NASAL CONGESTION	2 (2.5%)	(0.0%)	2 (2.3%)	(0.0%)	4 (1.3%)
COUGHING AND ASSOCIATED SYMPTOMS	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
COUGH	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
SINUS CONGESTION	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
BREATHING ABNORMALITIES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
DYSPNOEA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PHARYNGEAL DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
TONSILLOLITH	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RHINORRHOEA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	12 (15.0%)	15 (21.4%)	11 (12.6%)	18 (22.2%)	56 (17.6%)
URTICARIAS	7 (8.8%)	10 (14.3%)	10 (11.5%)	14 (17.3%)	41 (12.9%)
IDIOPATHIC URTICARIA	3 (3.8%)	6 (8.6%)	6 (6.9%)	11 (13.6%)	26 (8.2%)
URTICARIA	4 (5.0%)	4 (5.7%)	4 (4.6%)	3 (3.7%)	15 (4.7%)
ANGIOEDEMAS	2 (2.5%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	7 (2.2%)
ANGIOEDEMA	2 (2.5%)	1 (1.4%)	2 (2.3%)	(0.0%)	5 (1.6%)
SWELLING FACE	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
ERYTHEMAS	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
ERYTHEMA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
RASH ERYTHEMATOUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RASHES, ERUPTIONS AND EXANTHEMS NEC	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
RASH	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
RASH MACULO-PAPULAR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ALOPECIAS	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ALOPECIA	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
APOCRINE AND ECCRINE GLAND DISORDERS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
NIGHT SWEATS	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PRURITUS NEC	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
PRURITUS	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
DERMATITIS AND ECZEMA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DERMATITIS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PHOTOSENSITIVITY CONDITIONS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
SUNBURN	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/12
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
PURPURA AND RELATED CONDITIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ECCHYMOSIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SURGICAL AND MEDICAL PROCEDURES					
- Overall -	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DENTAL OPERATION	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABORTION INDUCED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
JOINT THERAPEUTIC PROCEDURES	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
JOINT SURGERY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN LESION EXCISIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MOLE EXCISION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VASCULAR DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
HYPERTENSION	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/8.1
Treatment-Emergent Adverse Events Occurring While On Study with Incidence >=3% in Any Treatment Group
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	53 (66.3%)	55 (78.6%)	72 (82.8%)	57 (70.4%)	237 (74.5%)
GASTROINTESTINAL DISORDERS					
- Overall -	7 (8.8%)	12 (17.1%)	9 (10.3%)	8 (9.9%)	36 (11.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	1 (1.3%)	4 (5.7%)	2 (2.3%)	2 (2.5%)	9 (2.8%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	3 (4.3%)	2 (2.3%)	2 (2.5%)	7 (2.2%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	4 (5.0%)	7 (10.0%)	8 (9.2%)	9 (11.1%)	28 (8.8%)
OEDEMA NEC	2 (2.5%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
OEDEMA PERIPHERAL	2 (2.5%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
FEBRILE DISORDERS	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
PYREXIA	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
INFECTIONS AND INFESTATIONS					
- Overall -	32 (40.0%)	29 (41.4%)	43 (49.4%)	26 (32.1%)	130 (40.9%)
UPPER RESPIRATORY TRACT INFECTIONS	23 (28.8%)	19 (27.1%)	25 (28.7%)	19 (23.5%)	86 (27.0%)
NASOPHARYNGITIS	16 (20.0%)	5 (7.1%)	14 (16.1%)	10 (12.3%)	45 (14.2%)
SINUSITIS	5 (6.3%)	6 (8.6%)	7 (8.0%)	5 (6.2%)	23 (7.2%)
UPPER RESPIRATORY TRACT INFECTION	3 (3.8%)	6 (8.6%)	4 (4.6%)	4 (4.9%)	17 (5.3%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	6 (7.5%)	5 (7.1%)	6 (6.9%)	2 (2.5%)	19 (6.0%)
BRONCHITIS	6 (7.5%)	5 (7.1%)	2 (2.3%)	2 (2.5%)	15 (4.7%)
LOWER RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	3 (3.4%)	(0.0%)	3 (0.9%)
URINARY TRACT INFECTIONS	3 (3.8%)	3 (4.3%)	7 (8.0%)	3 (3.7%)	16 (5.0%)
URINARY TRACT INFECTION	3 (3.8%)	3 (4.3%)	7 (8.0%)	2 (2.5%)	15 (4.7%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/8.1
Treatment-Emergent Adverse Events Occurring While On Study with Incidence >=3% in Any Treatment Group
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
EAR INFECTIONS	4 (5.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	6 (1.9%)
EAR INFECTION	3 (3.8%)	(0.0%)	(0.0%)	1 (1.2%)	4 (1.3%)
FUNGAL INFECTIONS NEC	1 (1.3%)	(0.0%)	4 (4.6%)	(0.0%)	5 (1.6%)
FUNGAL INFECTION	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	4 (5.0%)	9 (12.9%)	14 (16.1%)	12 (14.8%)	39 (12.3%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	4 (5.7%)	6 (6.9%)	5 (6.2%)	15 (4.7%)
ARTHRALGIA	(0.0%)	3 (4.3%)	5 (5.7%)	4 (4.9%)	12 (3.8%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	3 (3.8%)	3 (4.3%)	5 (5.7%)	4 (4.9%)	15 (4.7%)
BACK PAIN	3 (3.8%)	1 (1.4%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
PAIN IN EXTREMITY	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
NERVOUS SYSTEM DISORDERS					
- Overall -	7 (8.8%)	11 (15.7%)	18 (20.7%)	10 (12.3%)	46 (14.5%)
HEADACHES NEC	3 (3.8%)	5 (7.1%)	14 (16.1%)	7 (8.6%)	29 (9.1%)
HEADACHE	3 (3.8%)	5 (7.1%)	12 (13.8%)	7 (8.6%)	27 (8.5%)
MIGRAINE HEADACHES	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
MIGRAINE	(0.0%)	1 (1.4%)	3 (3.4%)	(0.0%)	4 (1.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	14 (17.5%)	7 (10.0%)	18 (20.7%)	5 (6.2%)	44 (13.8%)
BRONCHOSPASM AND OBSTRUCTION	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
ASTHMA	4 (5.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	11 (3.5%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Table 14.3/8.1
Treatment-Emergent Adverse Events Occurring While On Study with Incidence >=3% in Any Treatment Group
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
NASAL CONGESTION AND INFLAMMATIONS	3 (3.8%)	2 (2.9%)	4 (4.6%)	3 (3.7%)	12 (3.8%)
NASAL CONGESTION	3 (3.8%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	8 (2.5%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	5 (6.3%)	2 (2.9%)	5 (5.7%)	(0.0%)	12 (3.8%)
OROPHARYNGEAL PAIN	4 (5.0%)	2 (2.9%)	5 (5.7%)	(0.0%)	11 (3.5%)
COUGHING AND ASSOCIATED SYMPTOMS	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
COUGH	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	20 (25.0%)	25 (35.7%)	19 (21.8%)	25 (30.9%)	89 (28.0%)
URTICARIAS	13 (16.3%)	17 (24.3%)	14 (16.1%)	16 (19.8%)	60 (18.9%)
IDIOPATHIC URTICARIA	5 (6.3%)	10 (14.3%)	6 (6.9%)	11 (13.6%)	32 (10.1%)
URTICARIA	8 (10.0%)	9 (12.9%)	8 (9.2%)	5 (6.2%)	30 (9.4%)
ANGIOEDEMAS	5 (6.3%)	1 (1.4%)	3 (3.4%)	4 (4.9%)	13 (4.1%)
ANGIOEDEMA	3 (3.8%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
PRURITUS NEC	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
PRURITUS	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
VASCULAR DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
HYPERTENSION	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/31
Patients with Treatment-Emergent Adverse Events Suspected to be Caused by Study Drug Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	4 (5.0%)	6 (8.6%)	9 (10.3%)	14 (17.3%)	33 (10.4%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THROMBOCYTOPENIAS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THROMBOCYTOPENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
EAR AND LABYRINTH DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INNER EAR SIGNS AND SYMPTOMS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
VERTIGO	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EYE DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CONJUNCTIVAL INFECTIONS, IRRITATIONS AND INFLAMMATIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CONJUNCTIVITIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
LACRIMAL DISORDERS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DRY EYE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GASTROINTESTINAL DISORDERS					
- Overall -	(0.0%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
DIARRHOEA (EXCL INFECTIVE)	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
DIARRHOEA	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics(dharas1) pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/31
Patients with Treatment-Emergent Adverse Events Suspected to be Caused by Study Drug Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS					
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ABDOMINAL PAIN UPPER	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
ABDOMINAL PAIN LOWER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LIP SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
- Overall -	1 (1.3%)	1 (1.4%)	2 (2.3%)	5 (6.2%)	9 (2.8%)
INJECTION SITE REACTIONS	1 (1.3%)	(0.0%)	1 (1.1%)	3 (3.7%)	5 (1.6%)
INJECTION SITE HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE PAIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJECTION SITE PRURITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INJECTION SITE URTICARIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
OEDEMA NEC	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
OEDEMA PERIPHERAL	1 (1.3%)	1 (1.4%)	(0.0%)	1 (1.2%)	3 (0.9%)
ASTHENIC CONDITIONS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ASTHENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
GENERAL SIGNS AND SYMPTOMS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics[redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/31
Patients with Treatment-Emergent Adverse Events Suspected to be Caused by Study Drug Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS					
INFECTIONS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RESPIRATORY TRACT INFECTION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BRONCHITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INVESTIGATIONS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
PHYSICAL EXAMINATION PROCEDURES AND ORGAN	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
SYSTEM STATUS					
WEIGHT DECREASED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
WEIGHT INCREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
AND DISCOMFORT					
PAIN IN EXTREMITY	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
JOINT RELATED SIGNS AND SYMPTOMS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ARTHRALGIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS					
- Overall -	(0.0%)	3 (4.3%)	2 (2.3%)	5 (6.2%)	10 (3.1%)
HEADACHES NEC	(0.0%)	1 (1.4%)	2 (2.3%)	4 (4.9%)	7 (2.2%)
HEADACHE	(0.0%)	1 (1.4%)	2 (2.3%)	4 (4.9%)	7 (2.2%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
DIZZINESS	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics[redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/31
Patients with Treatment-Emergent Adverse Events Suspected to be Caused by Study Drug Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
NERVOUS SYSTEM DISORDERS					
SENSORY ABNORMALITIES NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HYPOAESTHESIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	2 (2.5%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	8 (2.5%)
ALOPECIAS	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
ALOPECIA	(0.0%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	4 (1.3%)
MADAROSIS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANGIOEDEMAS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANGIOEDEMA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
DERMAL AND EPIDERMAL CONDITIONS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PAIN OF SKIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DERMATITIS AND ECZEMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ECZEMA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
PRURITUS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PRURITUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
URTICARIAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
URTICARIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics[redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	-Total-	32 (40.0%)	36 (51.4%)	45 (51.7%)	38 (46.9%)	151 (47.5%)
	Mild	19 (23.8%)	14 (20.0%)	20 (23.0%)	15 (18.5%)	68 (21.4%)
	Moderate	12 (15.0%)	19 (27.1%)	21 (24.1%)	13 (16.0%)	65 (20.4%)
	Severe	1 (1.3%)	3 (4.3%)	4 (4.6%)	10 (12.3%)	18 (5.7%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANAEMIAS NEC	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
LEUKOCYTOSES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
ANAEMIA DEFICIENCIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
CARDIAC DISORDERS						
- Overall -	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MYOCARDIAL DISORDERS NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
EAR AND LABYRINTH DISORDERS						
- Overall -	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INNER EAR SIGNS AND SYMPTOMS	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ENDOCRINE DISORDERS						
- Overall -	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THYROID HYPOFUNCTION DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS						
- Overall -	-Total-	2 (2.5%)	5 (7.1%)	4 (4.6%)	4 (4.9%)	15 (4.7%)
	Mild	1 (1.3%)	4 (5.7%)	3 (3.4%)	4 (4.9%)	12 (3.8%)
	Moderate	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NAUSEA AND VOMITING SYMPTOMS	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GASTROINTESTINAL DISORDERS						
DENTAL PAIN AND SENSATION DISORDERS	-Total-	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
GASTROINTESTINAL AND ABDOMINAL PAINS (EXCL ORAL AND THROAT)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
DYSPEPTIC SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GASTRITIS (EXCL INFECTIVE)	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NON-SITE SPECIFIC GASTROINTESTINAL HAEMORRHAGES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ORAL SOFT TISSUE SWELLING AND OEDEMA	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
STOMATITIS AND ULCERATION	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
- Overall -	-Total-	2 (2.5%)	5 (7.1%)	1 (1.1%)	2 (2.5%)	10 (3.1%)
	Mild	2 (2.5%)	1 (1.4%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Moderate	(0.0%)	4 (5.7%)	(0.0%)	2 (2.5%)	6 (1.9%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class / High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
GENERAL SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	3 (4.3%)	(0.0%)	1 (1.2%)	5 (1.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	2 (2.9%)	(0.0%)	1 (1.2%)	3 (0.9%)
OEDEMA NEC	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
PAIN AND DISCOMFORT NEC	-Total-	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
ASTHENIC CONDITIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THERAPEUTIC AND NONTHERAPEUTIC RESPONSES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	(0.0%)	3 (3.7%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
ALLERGIES TO FOODS, FOOD ADDITIVES, DRUGS AND OTHER CHEMICALS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ALLERGIC CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

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Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
IMMUNE SYSTEM DISORDERS						
ANAPHYLACTIC RESPONSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFESTATIONS						
- Overall -	-Total-	15 (18.8%)	12 (17.1%)	22 (25.3%)	14 (17.3%)	63 (19.8%)
	Mild	14 (17.5%)	8 (11.4%)	13 (14.9%)	9 (11.1%)	44 (13.8%)
	Moderate	1 (1.3%)	4 (5.7%)	9 (10.3%)	5 (6.2%)	19 (6.0%)
UPPER RESPIRATORY TRACT INFECTIONS	-Total-	9 (11.3%)	8 (11.4%)	10 (11.5%)	9 (11.1%)	36 (11.3%)
	Mild	9 (11.3%)	6 (8.6%)	7 (8.0%)	5 (6.2%)	27 (8.5%)
	Moderate	(0.0%)	2 (2.9%)	3 (3.4%)	4 (4.9%)	9 (2.8%)
LOWER RESPIRATORY TRACT AND LUNG INFECTIONS	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
URINARY TRACT INFECTIONS	-Total-	(0.0%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	6 (1.9%)
	Mild	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
VIRAL INFECTIONS NEC	-Total-	(0.0%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	5 (1.6%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN STRUCTURES AND SOFT TISSUE INFECTIONS	-Total-	1 (1.3%)	(0.0%)	3 (3.4%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class / High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
BACTERIAL INFECTIONS NEC	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DENTAL AND ORAL SOFT TISSUE INFECTIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	1 (1.2%)	3 (0.9%)
STREPTOCOCCAL INFECTIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
HERPES VIRAL INFECTIONS	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
CANDIDA INFECTIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EAR INFECTIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
FUNGAL INFECTIONS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INFLUENZA VIRAL INFECTIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MYCOPLASMA INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
STAPHYLOCOCCAL INFECTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INFECTIONS AND INFESTATIONS						
TINEA INFECTIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS						
- Overall -	-Total-	2 (2.5%)	2 (2.9%)	1 (1.1%)	3 (3.7%)	8 (2.5%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Moderate	1 (1.3%)	1 (1.4%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NON-SITE SPECIFIC INJURIES NEC	-Total-	1 (1.3%)	2 (2.9%)	1 (1.1%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
LOWER LIMB FRACTURES AND DISLOCATIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
SKIN INJURIES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CEREBRAL INJURIES NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE, TENDON AND LIGAMENT INJURIES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THORACIC CAGE FRACTURES AND DISLOCATIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Severe	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INVESTIGATIONS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	7 (2.2%)
	Mild	1 (1.3%)	1 (1.4%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
VASCULAR TESTS NEC (INCL BLOOD PRESSURE)	-Total-	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
	Mild	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
CHOLESTEROL ANALYSES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HEART RATE AND PULSE INVESTIGATIONS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MINERAL AND ELECTROLYTE ANALYSES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
WHITE BLOOD CELL ANALYSES	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS						
- Overall -	-Total-	(0.0%)	(0.0%)	(0.0%)	2 (2.5%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
APPETITE DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
METABOLISM AND NUTRITION DISORDERS						
HYPOGLYCAEMIC CONDITIONS NEC	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Severe	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
- Overall -	-Total-	3 (3.8%)	3 (4.3%)	5 (5.7%)	5 (6.2%)	16 (5.0%)
	Mild	1 (1.3%)	2 (2.9%)	2 (2.3%)	4 (4.9%)	9 (2.8%)
	Moderate	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
JOINT RELATED SIGNS AND SYMPTOMS	-Total-	(0.0%)	3 (4.3%)	3 (3.4%)	2 (2.5%)	8 (2.5%)
	Mild	(0.0%)	2 (2.9%)	1 (1.1%)	2 (2.5%)	5 (1.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	-Total-	2 (2.5%)	(0.0%)	2 (2.3%)	2 (2.5%)	6 (1.9%)
	Mild	1 (1.3%)	(0.0%)	2 (2.3%)	2 (2.5%)	5 (1.6%)
	Severe	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
EXTREMITY DEFORMITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCLE PAINS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
MUSCLE RELATED SIGNS AND SYMPTOMS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
TENDON DISORDERS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NERVOUS SYSTEM DISORDERS						
- Overall -	-Total-	3 (3.8%)	4 (5.7%)	4 (4.6%)	2 (2.5%)	13 (4.1%)
	Mild	2 (2.5%)	3 (4.3%)	3 (3.4%)	2 (2.5%)	10 (3.1%)
	Moderate	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
HEADACHES NEC	-Total-	1 (1.3%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	8 (2.5%)
	Mild	(0.0%)	1 (1.4%)	3 (3.4%)	2 (2.5%)	6 (1.9%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
SENSORY ABNORMALITIES NEC	-Total-	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
	Mild	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
MIGRAINE HEADACHES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
NARCOLEPSY AND HYPERSOMNIA	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
NEUROLOGICAL SIGNS AND SYMPTOMS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
OLFACTORY NERVE DISORDERS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

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PSYCHIATRIC DISORDERS						
- Overall -	-Total-	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Mild	1 (1.3%)	1 (1.4%)	2 (2.3%)	(0.0%)	4 (1.3%)
ANXIETY SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
DISTURBANCES IN INITIATING AND MAINTAINING SLEEP	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
EMOTIONAL AND MOOD DISTURBANCES NEC	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SEXUAL DESIRE DISORDERS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RENAL AND URINARY DISORDERS						
- Overall -	-Total-	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RENAL LITHIASIS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
URINARY TRACT LITHIASIS (EXCL RENAL)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
- Overall -	-Total-	2 (2.5%)	(0.0%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	Mild	2 (2.5%)	(0.0%)	(0.0%)	1 (1.2%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class / High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS						
OVARIAN AND FALLOPIAN TUBE CYSTS AND NEOPLASMS	-Total-	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	(0.0%)	2 (2.3%)	(0.0%)	2 (0.6%)
CERVIX DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
MENSTRUATION WITH INCREASED BLEEDING	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
PROSTATIC SIGNS, SYMPTOMS AND DISORDERS NEC	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS						
- Overall -	-Total-	6 (7.5%)	2 (2.9%)	7 (8.0%)	1 (1.2%)	16 (5.0%)
	Mild	4 (5.0%)	2 (2.9%)	3 (3.4%)	1 (1.2%)	10 (3.1%)
	Moderate	2 (2.5%)	(0.0%)	3 (3.4%)	(0.0%)	5 (1.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
BRONCHOSPASM AND OBSTRUCTION	-Total-	3 (3.8%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	7 (2.2%)
	Mild	2 (2.5%)	1 (1.4%)	(0.0%)	1 (1.2%)	4 (1.3%)
	Moderate	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
NASAL CONGESTION AND INFLAMMATIONS	-Total-	2 (2.5%)	(0.0%)	2 (2.3%)	(0.0%)	4 (1.3%)
	Mild	2 (2.5%)	(0.0%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS						
COUGHING AND ASSOCIATED SYMPTOMS	-Total-	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
	Mild	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
PARANASAL SINUS DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Mild	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
BREATHING ABNORMALITIES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Moderate	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PHARYNGEAL DISORDERS (EXCL INFECTIONS AND NEOPLASMS)	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
UPPER RESPIRATORY TRACT SIGNS AND SYMPTOMS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
	Moderate	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
- Overall -	-Total-	12 (15.0%)	15 (21.4%)	11 (12.6%)	18 (22.2%)	56 (17.6%)
	Mild	4 (5.0%)	4 (5.7%)	(0.0%)	4 (4.9%)	12 (3.8%)
	Moderate	8 (10.0%)	9 (12.9%)	8 (9.2%)	7 (8.6%)	32 (10.1%)
	Severe	(0.0%)	2 (2.9%)	3 (3.4%)	7 (8.6%)	12 (3.8%)
URTICARIAS	-Total-	7 (8.8%)	10 (14.3%)	10 (11.5%)	14 (17.3%)	41 (12.9%)
	Mild	1 (1.3%)	2 (2.9%)	(0.0%)	1 (1.2%)	4 (1.3%)
	Moderate	6 (7.5%)	6 (8.6%)	7 (8.0%)	6 (7.4%)	25 (7.9%)
	Severe	(0.0%)	2 (2.9%)	3 (3.4%)	7 (8.6%)	12 (3.8%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS						
ANGIOEDEMAS	-Total-	2 (2.5%)	1 (1.4%)	3 (3.4%)	1 (1.2%)	7 (2.2%)
	Moderate	2 (2.5%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	6 (1.9%)
	Severe	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ERYTHEMAS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	2 (2.5%)	3 (0.9%)
RASHES, ERUPTIONS AND EXANTHEMS NEC	-Total-	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
	Mild	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
ALOPECIAS	-Total-	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	Moderate	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
APOCRINE AND ECCRINE GLAND DISORDERS	-Total-	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
PRURITUS NEC	-Total-	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Moderate	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
DERMATITIS AND ECZEMA	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PHOTOSENSITIVITY CONDITIONS	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
PURPURA AND RELATED CONDITIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/13
Patients with Treatment-Emergent Adverse Events Occurring During the Follow-up Period by Maximum Severity
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term	Severity	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SURGICAL AND MEDICAL PROCEDURES						
- Overall -	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	4 (1.3%)
DENTAL AND GINGIVAL THERAPEUTIC PROCEDURES	-Total-	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
JOINT THERAPEUTIC PROCEDURES	-Total-	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SKIN LESION EXCISIONS	-Total-	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	Mild	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
VASCULAR DISORDERS						
- Overall -	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
VASCULAR HYPERTENSIVE DISORDERS NEC	-Total-	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
	Mild	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)

Multiple occurrences of a specific adverse event for a patient were counted once by the maximum severity of these occurrences.
Includes treatment-emergent adverse events that started after the end of the treatment period (Week 24 or treatment discontinuation) through the last day in study.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_aesev)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/5
Patients with Treatment-Emergent Serious Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
-Any adverse events-	5 (6.3%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	14 (4.4%)
CARDIAC DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ISCHAEMIC CORONARY ARTERY DISORDERS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGINA UNSTABLE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL DISORDERS					
- Overall -	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROINTESTINAL ATONIC AND HYPOMOTILITY DISORDERS NEC	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
GASTROOESOPHAGEAL REFLUX DISEASE	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
IMMUNE SYSTEM DISORDERS					
- Overall -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC RESPONSES	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
ANAPHYLACTIC REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
INFECTIONS AND INFESTATIONS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABDOMINAL AND GASTROINTESTINAL INFECTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
APPENDICITIS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/5
Patients with Treatment-Emergent Serious Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
UPPER LIMB FRACTURES AND DISLOCATIONS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RADIUS FRACTURE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
METABOLISM AND NUTRITION DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
DIABETES MELLITUS (INCL SUBTYPES)	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
TYPE 2 DIABETES MELLITUS	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HYPOGLYCAEMIC CONDITIONS NEC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
SHOCK HYPOGLYCAEMIC	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE PAIN AND DISCOMFORT	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
PAIN IN EXTREMITY	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVIX DISORDERS NEC	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CERVICAL DYSPLASIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
- Overall -	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
BRONCHOSPASM AND OBSTRUCTION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/5
Patients with Treatment-Emergent Serious Adverse Events Occurring While On Study
Safety-Evaluable Patients

MedDRA System Organ Class High Level Term Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
- Overall -	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
URTICARIAS	1 (1.3%)	1 (1.4%)	1 (1.1%)	(0.0%)	3 (0.9%)
URTICARIA	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
IDIOPATHIC URTICARIA	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
ANGIOEDEMAS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGIOEDEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
SURGICAL AND MEDICAL PROCEDURES					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INDUCED ABORTIONS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ABORTION INDUCED	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VASCULAR DISORDERS					
- Overall -	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
VASCULAR HYPERTENSIVE DISORDERS NEC	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HYPERTENSION	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

Multiple occurrences of a specific adverse event for a patient were counted once in the frequency for the adverse event. Similarly, multiple occurrences of adverse events within a specific system organ class for a patient were counted once in the frequency for the system organ class. Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae)
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Table 14.3/15
Patients with Treatment-Emergent Adverse Events Considered Possible Components of Anaphylaxis Occurring While On Study
Safety-Evaluable Patients

Anaphylactic Reaction (SMQ)	Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Narrow Search	- Total -	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	ANAPHYLACTIC REACTION	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
Broad Search	- Total -	18 (22.5%)	17 (24.3%)	22 (25.3%)	13 (16.0%)	70 (22.0%)
	URTICARIA	8 (10.0%)	9 (12.9%)	8 (9.2%)	5 (6.2%)	30 (9.4%)
	ASTHMA	4 (5.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	11 (3.5%)
	COUGH	3 (3.8%)	4 (5.7%)	3 (3.4%)	(0.0%)	10 (3.1%)
	ANGIOEDEMA	3 (3.8%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
	PRURITUS	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
	ABDOMINAL PAIN UPPER	1 (1.3%)	1 (1.4%)	2 (2.3%)	1 (1.2%)	5 (1.6%)
	SWELLING FACE	2 (2.5%)	(0.0%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
	RASH	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
	ABDOMINAL PAIN	1 (1.3%)	(0.0%)	1 (1.1%)	(0.0%)	2 (0.6%)
	CHEST DISCOMFORT	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
	ERYTHEMA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
	LIP SWELLING	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
	WHEEZING	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)
	ABDOMINAL PAIN LOWER	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	DYSPNOEA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	GASTROINTESTINAL PAIN	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	INJECTION SITE URTICARIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	RASH ERYTHEMATOUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
	SWELLING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
	VOMITING	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
Algorithmic Search	- Total -	3 (3.8%)	5 (7.1%)	2 (2.3%)	3 (3.7%)	13 (4.1%)

SMQ=Standardized MedDRA Query. The narrow search contains preferred terms that represent core anaphylactic reaction terms (Category A). The broad search contains additional terms that are signs and symptoms possibly indicative of anaphylactic reaction (Category B, C, D, or E). The algorithmic search requires a patient to have a narrow term (Category A) or at least one of the following combinations of these signs and symptoms: Category (B and C) or (D and (B or C)) or (E and (B or C or D)), where Category B represents Upper Airway/Respiratory symptoms, Category C represents Angioedema/Urticaria/Pruritus/Flush symptoms, Category D represents Cardiovascular/Hypotension symptoms and Category E represents Gastrointestinal symptoms. A patient with multiple occurrences of an AE within the narrow search is counted only once in the AE category. A patient with multiple AEs within a search is counted only once in the total row. Includes treatment-emergent adverse events that started on or after the first treatment date.
Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_anaph)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:10 Page 1 of 1

Table 14.3/16
Patients with Treatment-Emergent Adverse Events Considered Possible Components of Churg-Strauss Occurring While On Study
Safety-Evaluable Patients

No observations

Includes treatment-emergent adverse events that started on or after the first treatment date.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_css)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:11 Page 1 of 1

Table 14.3/17
Patients with Treatment-Emergent Adverse Events Considered Possible Hypersensitivity Reactions Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Hypersensitivity (excluding anaphylaxis, injection site reaction, skin rash and urticaria)	10 (12.5%)	3 (4.3%)	9 (10.3%)	9 (11.1%)	31 (9.7%)
ASTHMA	4 (5.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	11 (3.5%)
ANGIOEDEMA	3 (3.8%)	1 (1.4%)	2 (2.3%)	3 (3.7%)	9 (2.8%)
SWELLING FACE	2 (2.5%)	(0.0%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
CHEST DISCOMFORT	(0.0%)	2 (2.9%)	(0.0%)	(0.0%)	2 (0.6%)
DRUG HYPERSENSITIVITY	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
HYPERSENSITIVITY	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
LIP SWELLING	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)

A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_hyp)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:12 Page 1 of 1

Table 14.3/18
Patients with Treatment-Emergent Adverse Events Considered Possible Injection-Site Reactions Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Extravasation Events (Injections, Infusions and Implants) (SMQ)	1 (1.3%)	1 (1.4%)	(0.0%)	(0.0%)	2 (0.6%)
INJECTION SITE PAIN	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
LOCAL SWELLING	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_inj)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/19
Patients with Treatment-Emergent Adverse Events Considered Possible Skin Rash Events Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Skin Rashes	4 (5.0%)	5 (7.1%)	2 (2.3%)	3 (3.7%)	14 (4.4%)
PRURITUS	1 (1.3%)	3 (4.3%)	1 (1.1%)	2 (2.5%)	7 (2.2%)
RASH	1 (1.3%)	2 (2.9%)	(0.0%)	(0.0%)	3 (0.9%)
ERYTHEMA	1 (1.3%)	(0.0%)	(0.0%)	1 (1.2%)	2 (0.6%)
INJECTION SITE PRURITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
RASH ERYTHEMATOUS	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RASH MACULO-PAPULAR	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)

A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_skin)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:13 Page 1 of 1

Table 14.3/20

Patients with Treatment-Emergent Adverse Events Considered Possible Components of Serum Sickness Syndrome Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Serum Sickness (PT)	(0.0%)	(0.0%)	(0.0%)	(0.0%)	(0.0%)
Number of patients with an event in Category A and Category B	(0.0%)	2 (2.9%)	4 (4.6%)	1 (1.2%)	7 (2.2%)
Category A events	(0.0%)	2 (2.9%)	4 (4.6%)	1 (1.2%)	7 (2.2%)
URTICARIA	(0.0%)	2 (2.9%)	1 (1.1%)	1 (1.2%)	4 (1.3%)
IDIOPATHIC URTICARIA	(0.0%)	2 (2.9%)	1 (1.1%)	(0.0%)	3 (0.9%)
ECZEMA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
INJECTION SITE PRURITUS	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
Category B events	(0.0%)	2 (2.9%)	4 (4.6%)	1 (1.2%)	7 (2.2%)
ARTHRALGIA	(0.0%)	(0.0%)	2 (2.3%)	1 (1.2%)	3 (0.9%)
PYREXIA	(0.0%)	1 (1.4%)	2 (2.3%)	(0.0%)	3 (0.9%)
INFLUENZA LIKE ILLNESS	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)

Patients are considered to have serum sickness syndrome if they have an adverse event with a preferred term of ‘Serum sickness‘; or if they experience at least one adverse event from category A (skin) and at least one adverse event from category B (generalized).
Preferred terms are sorted within group by descending frequency. Only patients who had an event in both categories (A and B) are included.
A patient with multiple occurrences of an AE is counted only once in the AE category.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_sss)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:14 Page 1 of 1

Table 14.3/21
Patients with Treatment-Emergent Adverse Events Considered Possible Malignancies Occurring While On Study
Safety-Evaluable Patients

No observations

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_malig)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:15 Page 1 of 1

Table 14.3/22

Patients with Treatment-Emergent Adverse Events Considered Possible Thrombocytopenia and Bleeding Related Events Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Thrombocytopenia (Subgroup of Haematopoietic cytopenias SMQ)	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
THROMBOCYTOPENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
Haemorrhages (SMQ)	2 (2.5%)	2 (2.9%)	1 (1.1%)	5 (6.2%)	10 (3.1%)
ECCHYMOSIS	(0.0%)	1 (1.4%)	(0.0%)	1 (1.2%)	2 (0.6%)
MENORRHAGIA	(0.0%)	(0.0%)	1 (1.1%)	1 (1.2%)	2 (0.6%)
CONTUSION	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
GINGIVAL BLEEDING	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMATOCHEZIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
HAEMOGLOBIN DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
HAEMORRHAGIC ANAEMIA	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
INJECTION SITE HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
RECTAL HAEMORRHAGE	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_throm)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:16 Page 1 of 1

Table 14.3/23
Patients with Treatment-Emergent Adverse Events Considered Possible Haematopoietic Cytopenias Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Haematopoietic cytopenias (SMQ)	(0.0%)	(0.0%)	2 (2.3%)	3 (3.7%)	5 (1.6%)
ANAEMIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
HAEMOGLOBIN DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
NEUTROPENIA	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
THROMBOCYTOPENIA	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
WHITE BLOOD CELL COUNT DECREASED	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_hamcyto)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/24

Patients with Treatment-Emergent Adverse Events Considered Possible Arterial Thrombotic Events (ATEs) Occurring While On Study

Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Cardiac Ishaemic Events	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)
ANGINA UNSTABLE	(0.0%)	(0.0%)	1 (1.1%)	(0.0%)	1 (0.3%)

A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_ate)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/25
Patients with Treatment-Emergent Adverse Events Considered Possible Asthma/Bronchospasm Events Occurring While On Study
Safety-Evaluable Patients

AE of Special Interest Preferred Term	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Patients (n=318)
Asthma/Bronchospasm (SMQ)	4 (5.0%)	2 (2.9%)	5 (5.7%)	2 (2.5%)	13 (4.1%)
ASTHMA	4 (5.0%)	1 (1.4%)	4 (4.6%)	2 (2.5%)	11 (3.5%)
WHEEZING	(0.0%)	1 (1.4%)	1 (1.1%)	(0.0%)	2 (0.6%)

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_asthbr)
Database (CLOSED) Datasets (dae pat)
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Table 14.3/26
Patients with Treatment-Emergent Adverse Events Considered Possible Liver-related investigations, signs and symptoms Occurring
Safety-Evaluable Patients

No observations

SMQ=Standardized MedDRA Query.
A patient with multiple different events within a special interest category is counted once in the category total.
A patient with multiple occurrences of an event of special interest is counted once within the event.
Includes treatment-emergent adverse events that started on or after the first treatment date.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_ae_liver)
Database (CLOSED) Datasets (dae pat)
: Generated 19MAR13 08:19 Page 1 of 1

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03					
Omalizumab 75mg	70	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02					
Omalizumab 150mg	86	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02					
Omalizumab 300mg	81	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03					
Week 4																
Placebo	72	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	-0.02	0.03
Omalizumab 75mg	66	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.01	-0.00	0.00	-0.00	-0.02	0.01
Omalizumab 150mg	83	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.02	0.01
Omalizumab 300mg	76	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	-0.03	0.02
Week 8																
Placebo	65	0.01	0.00	0.01	0.00	0.03	0.00	0.00	0.00	0.00	0.02	-0.00	0.00	0.00	-0.01	0.01
Omalizumab 75mg	62	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.03	-0.00	0.00	0.00	-0.01	0.02
Omalizumab 150mg	76	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	-0.02	0.02
Omalizumab 300mg	73	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	-0.03	0.02
Week 12																
Placebo	64	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.00	0.00	-0.02	0.01
Omalizumab 75mg	61	0.01	0.00	0.01	0.00	0.02	0.01	0.01	0.01	0.00	0.03	0.00	0.01	0.00	-0.01	0.02
Omalizumab 150mg	75	0.01	0.00	0.01	0.00	0.02	0.01	0.01	0.01	0.00	0.04	0.00	0.01	0.00	-0.01	0.03
Omalizumab 300mg	69	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	-0.03	0.02
Week 16																
Placebo	61	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.00	0.00	0.02	-0.00	0.00	0.00	-0.02	0.02
Omalizumab 75mg	59	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.01	0.01
Omalizumab 150mg	69	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.02	0.01
Omalizumab 300mg	73	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	-0.03	0.01
Week 20																
Placebo	59	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.02	0.01
Omalizumab 75mg	60	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	0.00	0.00	0.00	-0.01	0.01
Omalizumab 150mg	68	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.03	-0.00	0.01	-0.00	-0.02	0.02
Omalizumab 300mg	72	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	-0.03	0.02

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hemato)
Database (CLOSED) Datasets (labv)
: Generated 25JAN13 10:15 Page 1 of 30

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.00	0.00	-0.01	0.02
Omalizumab 75mg	64	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.01	0.02
Omalizumab 150mg	76	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	0.00	0.00	0.00	-0.01	0.01
Omalizumab 300mg	73	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	-0.02	0.02
Week 32																
Placebo	62	0.01	0.00	0.01	0.00	0.03	0.00	0.00	0.00	0.00	0.02	-0.00	0.00	-0.00	-0.02	0.01
Omalizumab 75mg	56	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.02	0.02
Omalizumab 150mg	71	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.01	0.02
Omalizumab 300mg	65	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	-0.00	0.01	0.00	-0.03	0.01
Week 40																
Placebo	62	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.00	0.00	-0.02	0.01
Omalizumab 75mg	55	0.01	0.00	0.01	0.00	0.02	0.01	0.01	0.01	0.00	0.03	0.00	0.01	0.00	-0.02	0.02
Omalizumab 150mg	69	0.01	0.00	0.01	0.00	0.02	0.01	0.00	0.01	0.00	0.02	-0.00	0.00	0.00	-0.01	0.01
Omalizumab 300mg	68	0.01	0.00	0.01	0.00	0.03	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	-0.03	0.02
Early Term																
Placebo	10	0.01	0.00	0.01	0.00	0.01	0.00	0.00	0.00	0.00	0.02	-0.00	0.00	-0.00	-0.01	0.01
Omalizumab 75mg	6	0.01	0.00	0.01	0.00	0.01	0.01	0.01	0.01	0.00	0.02	0.00	0.01	0.00	-0.00	0.02
Omalizumab 150mg	12	0.01	0.01	0.00	0.00	0.02	0.00	0.00	0.00	0.00	0.01	-0.00	0.00	-0.00	-0.01	0.00
Omalizumab 300mg	8	0.01	0.01	0.00	0.00	0.02	0.00	0.00	0.00	0.00	0.01	-0.00	0.01	-0.00	-0.02	0.00

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.05	0.03	0.04	0.00	0.14	0.05	0.03	0.04	0.00	0.14					
Omalizumab 75mg	70	0.04	0.03	0.04	0.01	0.16	0.04	0.03	0.04	0.01	0.16					
Omalizumab 150mg	86	0.05	0.03	0.04	0.00	0.16	0.05	0.03	0.04	0.00	0.16					
Omalizumab 300mg	81	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.04	0.00	0.17					
Week 4																
Placebo	72	0.05	0.03	0.04	0.01	0.14	0.04	0.04	0.04	0.00	0.31	-0.00	0.05	0.00	-0.10	0.28
Omalizumab 75mg	66	0.04	0.03	0.04	0.01	0.16	0.04	0.02	0.03	0.00	0.11	-0.01	0.03	0.00	-0.10	0.06
Omalizumab 150mg	83	0.04	0.03	0.04	0.00	0.16	0.04	0.03	0.04	0.00	0.13	-0.00	0.03	0.00	-0.12	0.10
Omalizumab 300mg	76	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.04	0.00	0.13	0.00	0.04	0.01	-0.17	0.12
Week 8																
Placebo	65	0.04	0.03	0.03	0.00	0.14	0.04	0.02	0.03	0.00	0.14	-0.01	0.03	0.00	-0.10	0.06
Omalizumab 75mg	62	0.05	0.03	0.04	0.01	0.16	0.04	0.04	0.03	0.00	0.23	-0.00	0.04	0.00	-0.07	0.19
Omalizumab 150mg	76	0.05	0.03	0.04	0.00	0.16	0.05	0.04	0.04	0.00	0.21	0.00	0.04	0.00	-0.09	0.19
Omalizumab 300mg	73	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.04	0.00	0.20	0.00	0.04	0.01	-0.13	0.15
Week 12																
Placebo	64	0.04	0.03	0.04	0.00	0.14	0.04	0.04	0.04	0.00	0.18	0.00	0.04	0.00	-0.09	0.14
Omalizumab 75mg	61	0.05	0.03	0.04	0.01	0.16	0.05	0.04	0.04	0.00	0.22	0.00	0.04	0.00	-0.09	0.11
Omalizumab 150mg	75	0.05	0.03	0.04	0.00	0.16	0.05	0.04	0.04	0.00	0.27	0.01	0.04	0.00	-0.08	0.19
Omalizumab 300mg	69	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.04	0.00	0.12	0.00	0.04	0.00	-0.16	0.10
Week 16																
Placebo	61	0.04	0.03	0.03	0.00	0.14	0.04	0.03	0.03	0.00	0.21	-0.00	0.04	0.00	-0.14	0.15
Omalizumab 75mg	59	0.04	0.03	0.04	0.01	0.16	0.04	0.03	0.03	0.00	0.17	-0.01	0.03	0.00	-0.08	0.06
Omalizumab 150mg	69	0.05	0.03	0.04	0.00	0.16	0.04	0.03	0.04	0.00	0.16	-0.00	0.03	0.00	-0.16	0.05
Omalizumab 300mg	73	0.04	0.03	0.03	0.00	0.17	0.04	0.03	0.04	0.00	0.17	0.00	0.03	0.01	-0.15	0.09
Week 20																
Placebo	59	0.04	0.03	0.04	0.00	0.14	0.04	0.03	0.03	0.00	0.12	-0.01	0.03	0.00	-0.10	0.06
Omalizumab 75mg	60	0.04	0.03	0.04	0.01	0.16	0.04	0.02	0.04	0.01	0.10	-0.00	0.02	0.00	-0.09	0.04
Omalizumab 150mg	68	0.05	0.03	0.04	0.00	0.16	0.04	0.03	0.04	0.00	0.20	-0.00	0.04	0.00	-0.12	0.12
Omalizumab 300mg	72	0.04	0.03	0.04	0.00	0.17	0.05	0.03	0.04	0.00	0.24	0.01	0.03	0.01	-0.17	0.15

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.05	0.03	0.04	0.00	0.14	0.05	0.04	0.03	0.00	0.21	0.00	0.04	0.00	-0.08	0.18
Omalizumab 75mg	64	0.04	0.03	0.03	0.01	0.16	0.04	0.03	0.04	0.00	0.15	-0.00	0.03	0.00	-0.10	0.08
Omalizumab 150mg	76	0.04	0.03	0.04	0.00	0.16	0.04	0.02	0.04	0.00	0.10	-0.00	0.03	0.00	-0.07	0.06
Omalizumab 300mg	73	0.04	0.03	0.03	0.00	0.17	0.05	0.03	0.04	0.00	0.18	0.01	0.04	0.00	-0.12	0.14
Week 32																
Placebo	62	0.05	0.03	0.04	0.00	0.14	0.04	0.03	0.03	0.00	0.12	-0.01	0.03	-0.01	-0.11	0.06
Omalizumab 75mg	56	0.04	0.03	0.04	0.01	0.16	0.04	0.04	0.03	0.00	0.18	-0.00	0.03	0.00	-0.10	0.12
Omalizumab 150mg	71	0.05	0.03	0.04	0.00	0.16	0.04	0.03	0.04	0.00	0.19	-0.00	0.03	0.00	-0.10	0.16
Omalizumab 300mg	65	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.03	0.00	0.22	0.00	0.03	0.01	-0.14	0.08
Week 40																
Placebo	62	0.05	0.03	0.04	0.00	0.14	0.04	0.03	0.04	0.01	0.14	-0.00	0.03	0.00	-0.10	0.10
Omalizumab 75mg	55	0.04	0.03	0.04	0.01	0.16	0.05	0.03	0.04	0.00	0.17	0.00	0.04	0.00	-0.16	0.14
Omalizumab 150mg	69	0.05	0.03	0.04	0.00	0.16	0.04	0.02	0.04	0.00	0.10	-0.00	0.03	0.00	-0.09	0.10
Omalizumab 300mg	68	0.04	0.03	0.04	0.00	0.17	0.04	0.03	0.03	0.00	0.21	0.00	0.03	0.00	-0.16	0.10
Early Term																
Placebo	10	0.04	0.02	0.04	0.01	0.07	0.03	0.03	0.03	0.00	0.09	-0.01	0.03	-0.01	-0.05	0.03
Omalizumab 75mg	6	0.04	0.02	0.04	0.01	0.06	0.07	0.04	0.07	0.01	0.11	0.03	0.03	0.04	-0.01	0.07
Omalizumab 150mg	12	0.04	0.04	0.03	0.01	0.11	0.04	0.03	0.03	0.00	0.10	-0.01	0.03	0.01	-0.08	0.02
Omalizumab 300mg	8	0.04	0.03	0.03	0.00	0.10	0.03	0.02	0.04	0.00	0.08	-0.00	0.04	0.00	-0.06	0.06

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.02	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.15					
Omalizumab 75mg	70	0.03	0.03	0.02	0.00	0.23	0.03	0.03	0.02	0.00	0.23					
Omalizumab 150mg	86	0.03	0.02	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.15					
Omalizumab 300mg	81	0.03	0.02	0.02	0.01	0.11	0.03	0.02	0.02	0.01	0.11					
Week 4																
Placebo	72	0.03	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.08	-0.00	0.01	0.00	-0.08	0.03
Omalizumab 75mg	66	0.03	0.03	0.02	0.01	0.23	0.03	0.02	0.02	0.00	0.08	-0.00	0.02	-0.00	-0.14	0.05
Omalizumab 150mg	83	0.03	0.03	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.12	-0.00	0.01	0.00	-0.08	0.04
Omalizumab 300mg	76	0.03	0.02	0.02	0.01	0.11	0.03	0.02	0.02	0.00	0.11	0.00	0.01	0.00	-0.02	0.04
Week 8																
Placebo	65	0.03	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.10	-0.00	0.02	0.00	-0.09	0.05
Omalizumab 75mg	62	0.03	0.03	0.02	0.01	0.23	0.02	0.01	0.02	0.00	0.06	-0.01	0.03	-0.00	-0.20	0.03
Omalizumab 150mg	76	0.03	0.02	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.13	0.00	0.02	0.00	-0.10	0.05
Omalizumab 300mg	73	0.03	0.02	0.03	0.01	0.11	0.03	0.01	0.02	0.01	0.06	-0.00	0.01	-0.00	-0.06	0.03
Week 12																
Placebo	64	0.03	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.11	-0.00	0.02	-0.00	-0.12	0.06
Omalizumab 75mg	61	0.03	0.03	0.02	0.01	0.23	0.03	0.02	0.02	0.00	0.09	-0.00	0.03	0.00	-0.17	0.03
Omalizumab 150mg	75	0.03	0.03	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.13	0.00	0.02	0.00	-0.13	0.08
Omalizumab 300mg	69	0.03	0.02	0.03	0.01	0.11	0.03	0.02	0.02	0.01	0.09	0.00	0.01	0.00	-0.03	0.06
Week 16																
Placebo	61	0.02	0.02	0.02	0.00	0.15	0.02	0.01	0.02	0.00	0.09	-0.00	0.02	0.00	-0.12	0.04
Omalizumab 75mg	59	0.03	0.03	0.02	0.01	0.23	0.02	0.02	0.02	0.00	0.08	-0.00	0.03	0.00	-0.20	0.03
Omalizumab 150mg	69	0.03	0.03	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.12	-0.00	0.02	-0.00	-0.10	0.07
Omalizumab 300mg	73	0.03	0.02	0.03	0.01	0.11	0.02	0.01	0.02	0.01	0.10	-0.00	0.01	-0.00	-0.03	0.03
Week 20																
Placebo	59	0.03	0.02	0.02	0.00	0.15	0.02	0.01	0.02	0.00	0.08	-0.00	0.02	0.00	-0.11	0.03
Omalizumab 75mg	60	0.03	0.03	0.02	0.01	0.23	0.02	0.02	0.02	0.00	0.09	-0.00	0.02	-0.00	-0.14	0.04
Omalizumab 150mg	68	0.03	0.03	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.09	-0.00	0.02	-0.00	-0.13	0.04
Omalizumab 300mg	72	0.03	0.02	0.03	0.01	0.11	0.02	0.02	0.02	0.00	0.10	-0.00	0.02	-0.00	-0.10	0.09

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.02	0.02	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.08	0.00	0.02	0.00	-0.11	0.04
Omalizumab 75mg	64	0.03	0.03	0.02	0.01	0.23	0.03	0.02	0.02	0.01	0.07	-0.00	0.03	-0.00	-0.16	0.04
Omalizumab 150mg	76	0.03	0.03	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.15	-0.00	0.02	0.00	-0.11	0.10
Omalizumab 300mg	73	0.03	0.02	0.03	0.01	0.11	0.02	0.01	0.02	0.00	0.08	-0.00	0.01	-0.00	-0.06	0.03
Week 32																
Placebo	62	0.02	0.02	0.02	0.00	0.15	0.03	0.02	0.02	0.00	0.09	0.00	0.02	0.00	-0.11	0.06
Omalizumab 75mg	56	0.03	0.03	0.02	0.01	0.23	0.02	0.02	0.02	0.00	0.11	-0.01	0.03	-0.00	-0.18	0.06
Omalizumab 150mg	71	0.03	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.08	-0.01	0.02	-0.00	-0.13	0.05
Omalizumab 300mg	65	0.03	0.02	0.02	0.01	0.11	0.02	0.02	0.02	0.00	0.11	-0.00	0.01	-0.00	-0.05	0.04
Week 40																
Placebo	62	0.02	0.02	0.02	0.00	0.15	0.02	0.02	0.02	0.00	0.09	0.00	0.02	0.00	-0.12	0.05
Omalizumab 75mg	55	0.03	0.03	0.02	0.01	0.23	0.02	0.01	0.02	0.00	0.06	-0.01	0.03	0.00	-0.20	0.02
Omalizumab 150mg	69	0.03	0.03	0.02	0.00	0.15	0.03	0.03	0.02	0.00	0.14	-0.00	0.02	0.00	-0.11	0.07
Omalizumab 300mg	68	0.03	0.02	0.02	0.01	0.11	0.02	0.02	0.02	0.00	0.14	-0.00	0.01	-0.00	-0.02	0.03
Early Term																
Placebo	10	0.03	0.02	0.02	0.00	0.06	0.03	0.02	0.02	0.00	0.07	-0.00	0.02	-0.01	-0.03	0.04
Omalizumab 75mg	6	0.03	0.03	0.02	0.00	0.06	0.02	0.02	0.01	0.01	0.07	-0.01	0.02	-0.00	-0.06	0.01
Omalizumab 150mg	12	0.01	0.00	0.01	0.01	0.02	0.01	0.01	0.01	0.00	0.02	-0.00	0.01	-0.00	-0.01	0.01
Omalizumab 300mg	8	0.03	0.02	0.03	0.01	0.07	0.03	0.02	0.02	0.00	0.06	-0.00	0.01	-0.01	-0.02	0.02

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.19	0.20	0.16	0.00	1.71	0.19	0.20	0.16	0.00	1.71					
Omalizumab 75mg	70	0.19	0.23	0.15	0.02	1.84	0.19	0.23	0.15	0.02	1.84					
Omalizumab 150mg	86	0.19	0.17	0.14	0.00	0.97	0.19	0.17	0.14	0.00	0.97					
Omalizumab 300mg	81	0.19	0.11	0.18	0.04	0.62	0.19	0.11	0.18	0.04	0.62					
Week 4																
Placebo	72	0.19	0.21	0.17	0.00	1.71	0.17	0.12	0.14	0.01	0.73	-0.02	0.15	0.00	-0.98	0.22
Omalizumab 75mg	66	0.20	0.24	0.16	0.02	1.84	0.16	0.11	0.14	0.02	0.60	-0.04	0.17	-0.02	-1.28	0.29
Omalizumab 150mg	83	0.19	0.17	0.14	0.00	0.97	0.17	0.14	0.14	0.00	0.82	-0.02	0.09	-0.01	-0.57	0.10
Omalizumab 300mg	76	0.19	0.11	0.18	0.04	0.62	0.19	0.12	0.15	0.00	0.66	-0.00	0.08	0.00	-0.18	0.25
Week 8																
Placebo	65	0.20	0.22	0.17	0.00	1.71	0.17	0.12	0.14	0.00	0.65	-0.03	0.16	-0.01	-1.06	0.33
Omalizumab 75mg	62	0.20	0.25	0.15	0.02	1.84	0.15	0.09	0.15	0.01	0.42	-0.05	0.22	-0.02	-1.62	0.19
Omalizumab 150mg	76	0.19	0.16	0.14	0.00	0.97	0.19	0.15	0.14	0.00	0.85	0.00	0.12	0.01	-0.69	0.35
Omalizumab 300mg	73	0.19	0.11	0.18	0.04	0.62	0.19	0.10	0.16	0.04	0.46	-0.01	0.09	0.00	-0.25	0.19
Week 12																
Placebo	64	0.20	0.22	0.18	0.00	1.71	0.18	0.11	0.17	0.01	0.75	-0.02	0.20	0.00	-1.40	0.47
Omalizumab 75mg	61	0.20	0.25	0.15	0.02	1.84	0.18	0.12	0.14	0.01	0.70	-0.02	0.20	0.00	-1.47	0.18
Omalizumab 150mg	75	0.20	0.17	0.15	0.00	0.97	0.20	0.17	0.15	0.01	1.01	-0.00	0.14	0.00	-0.82	0.51
Omalizumab 300mg	69	0.19	0.11	0.19	0.04	0.62	0.18	0.09	0.16	0.06	0.56	-0.02	0.10	-0.01	-0.27	0.33
Week 16																
Placebo	61	0.20	0.22	0.17	0.00	1.71	0.18	0.12	0.15	0.01	0.56	-0.01	0.20	0.01	-1.39	0.28
Omalizumab 75mg	59	0.20	0.25	0.15	0.02	1.84	0.16	0.11	0.14	0.00	0.57	-0.04	0.22	0.00	-1.58	0.17
Omalizumab 150mg	69	0.20	0.18	0.14	0.00	0.97	0.18	0.15	0.15	0.00	1.03	-0.02	0.14	-0.02	-0.71	0.53
Omalizumab 300mg	73	0.19	0.11	0.18	0.04	0.62	0.16	0.08	0.15	0.03	0.42	-0.03	0.09	-0.02	-0.24	0.18
Week 20																
Placebo	59	0.20	0.23	0.18	0.00	1.71	0.19	0.12	0.16	0.01	0.51	-0.02	0.18	0.00	-1.21	0.28
Omalizumab 75mg	60	0.20	0.25	0.15	0.02	1.84	0.16	0.14	0.12	0.00	0.79	-0.04	0.19	-0.02	-1.25	0.39
Omalizumab 150mg	68	0.20	0.18	0.14	0.00	0.97	0.17	0.14	0.13	0.00	0.79	-0.02	0.15	0.00	-0.89	0.29
Omalizumab 300mg	72	0.19	0.11	0.19	0.04	0.62	0.18	0.16	0.14	0.02	1.18	-0.01	0.18	-0.02	-0.55	1.04

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hemato)
Database (CLOSED) Datasets (labv)
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Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.19	0.21	0.16	0.00	1.71	0.19	0.11	0.17	0.01	0.45	0.00	0.19	0.01	-1.26	0.36
Omalizumab 75mg	64	0.20	0.24	0.16	0.02	1.84	0.17	0.11	0.15	0.02	0.55	-0.03	0.20	-0.01	-1.36	0.21
Omalizumab 150mg	76	0.20	0.18	0.15	0.00	0.97	0.18	0.17	0.14	0.00	1.04	-0.02	0.17	0.00	-0.82	0.54
Omalizumab 300mg	73	0.19	0.11	0.19	0.04	0.62	0.17	0.08	0.15	0.04	0.44	-0.03	0.10	-0.01	-0.41	0.20
Week 32																
Placebo	62	0.19	0.22	0.16	0.01	1.71	0.20	0.15	0.14	0.01	0.66	0.01	0.22	0.00	-1.33	0.58
Omalizumab 75mg	56	0.20	0.25	0.16	0.02	1.84	0.16	0.12	0.13	0.01	0.73	-0.04	0.24	-0.00	-1.57	0.33
Omalizumab 150mg	71	0.20	0.16	0.15	0.00	0.97	0.17	0.13	0.14	0.00	0.64	-0.03	0.16	-0.01	-0.83	0.50
Omalizumab 300mg	65	0.19	0.11	0.17	0.04	0.62	0.16	0.10	0.14	0.03	0.52	-0.03	0.11	-0.02	-0.28	0.38
Week 40																
Placebo	62	0.19	0.22	0.17	0.00	1.71	0.18	0.12	0.16	0.01	0.65	-0.01	0.21	-0.02	-1.39	0.37
Omalizumab 75mg	55	0.20	0.26	0.16	0.02	1.84	0.16	0.09	0.14	0.03	0.42	-0.04	0.24	0.00	-1.69	0.21
Omalizumab 150mg	69	0.20	0.18	0.15	0.00	0.97	0.20	0.22	0.15	0.00	1.28	0.00	0.20	-0.01	-0.79	0.78
Omalizumab 300mg	68	0.19	0.11	0.18	0.04	0.62	0.17	0.10	0.16	0.03	0.54	-0.02	0.09	-0.03	-0.27	0.22
Early Term																
Placebo	10	0.20	0.17	0.15	0.02	0.53	0.18	0.13	0.17	0.00	0.40	-0.02	0.14	-0.01	-0.27	0.23
Omalizumab 75mg	6	0.21	0.19	0.16	0.05	0.57	0.13	0.10	0.08	0.06	0.30	-0.08	0.20	-0.01	-0.49	0.07
Omalizumab 150mg	12	0.11	0.04	0.10	0.05	0.18	0.09	0.04	0.09	0.03	0.15	-0.01	0.05	-0.02	-0.11	0.05
Omalizumab 300mg	8	0.20	0.10	0.21	0.06	0.35	0.19	0.09	0.19	0.04	0.31	-0.01	0.08	-0.04	-0.08	0.11

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.41	0.04	0.42	0.32	0.51	0.41	0.04	0.42	0.32	0.51					
Omalizumab 75mg	70	0.40	0.03	0.40	0.34	0.50	0.40	0.03	0.40	0.34	0.50					
Omalizumab 150mg	86	0.41	0.04	0.40	0.32	0.50	0.41	0.04	0.40	0.32	0.50					
Omalizumab 300mg	81	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.39	0.33	0.51					
Week 4																
Placebo	71	0.41	0.04	0.42	0.32	0.51	0.41	0.03	0.41	0.34	0.49	-0.00	0.03	0.00	-0.09	0.09
Omalizumab 75mg	66	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.33	0.46	0.00	0.02	0.00	-0.06	0.06
Omalizumab 150mg	82	0.40	0.04	0.40	0.32	0.50	0.40	0.03	0.40	0.30	0.50	-0.00	0.02	0.00	-0.06	0.05
Omalizumab 300mg	75	0.40	0.04	0.39	0.33	0.51	0.40	0.03	0.41	0.32	0.48	0.01	0.02	0.00	-0.05	0.06
Week 8																
Placebo	65	0.41	0.04	0.42	0.32	0.51	0.41	0.03	0.41	0.34	0.49	-0.00	0.03	0.00	-0.09	0.10
Omalizumab 75mg	62	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.35	0.50	0.00	0.02	0.00	-0.04	0.08
Omalizumab 150mg	76	0.41	0.04	0.40	0.32	0.50	0.40	0.04	0.40	0.33	0.48	-0.00	0.03	0.00	-0.08	0.08
Omalizumab 300mg	73	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.33	0.49	0.00	0.03	0.00	-0.06	0.10
Week 12																
Placebo	61	0.41	0.04	0.42	0.32	0.51	0.41	0.04	0.42	0.33	0.51	0.00	0.03	0.00	-0.07	0.09
Omalizumab 75mg	61	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.34	0.49	0.00	0.02	0.00	-0.05	0.06
Omalizumab 150mg	74	0.41	0.04	0.40	0.32	0.50	0.41	0.04	0.41	0.28	0.48	-0.00	0.03	0.00	-0.10	0.09
Omalizumab 300mg	69	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.32	0.49	0.00	0.03	0.00	-0.07	0.08
Week 16																
Placebo	61	0.41	0.04	0.42	0.32	0.51	0.41	0.04	0.41	0.34	0.49	-0.00	0.04	0.00	-0.08	0.09
Omalizumab 75mg	59	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.35	0.49	0.00	0.03	0.00	-0.06	0.06
Omalizumab 150mg	68	0.40	0.04	0.40	0.32	0.50	0.41	0.04	0.41	0.33	0.49	0.00	0.03	0.00	-0.09	0.10
Omalizumab 300mg	72	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.34	0.48	0.00	0.03	0.01	-0.06	0.07
Week 20																
Placebo	59	0.41	0.04	0.42	0.32	0.51	0.41	0.04	0.41	0.34	0.54	-0.00	0.04	0.00	-0.09	0.09
Omalizumab 75mg	60	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.34	0.49	0.00	0.02	0.00	-0.05	0.07
Omalizumab 150mg	68	0.41	0.04	0.40	0.32	0.50	0.41	0.03	0.41	0.33	0.50	0.00	0.03	0.01	-0.08	0.06
Omalizumab 300mg	72	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.30	0.49	-0.00	0.03	0.00	-0.08	0.07

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	64	0.41	0.04	0.43	0.32	0.51	0.41	0.03	0.41	0.33	0.48	-0.01	0.03	-0.01	-0.10	0.09
Omalizumab 75mg	63	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.35	0.48	0.00	0.02	0.00	-0.05	0.06
Omalizumab 150mg	76	0.41	0.04	0.40	0.32	0.50	0.41	0.04	0.41	0.34	0.50	0.00	0.03	0.00	-0.07	0.07
Omalizumab 300mg	73	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.33	0.50	0.01	0.02	0.01	-0.05	0.10
Week 32																
Placebo	62	0.41	0.04	0.43	0.32	0.51	0.41	0.04	0.42	0.33	0.51	-0.01	0.03	0.00	-0.10	0.10
Omalizumab 75mg	56	0.40	0.03	0.40	0.34	0.47	0.40	0.03	0.40	0.34	0.52	0.00	0.03	0.00	-0.07	0.08
Omalizumab 150mg	70	0.40	0.04	0.40	0.32	0.50	0.41	0.04	0.40	0.34	0.52	0.00	0.03	0.00	-0.06	0.08
Omalizumab 300mg	64	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.33	0.49	0.01	0.03	0.00	-0.06	0.06
Week 40																
Placebo	62	0.42	0.04	0.43	0.32	0.51	0.42	0.04	0.42	0.34	0.49	-0.00	0.03	0.01	-0.09	0.10
Omalizumab 75mg	55	0.40	0.03	0.40	0.34	0.47	0.41	0.03	0.41	0.35	0.50	0.00	0.02	0.00	-0.04	0.05
Omalizumab 150mg	69	0.40	0.04	0.40	0.32	0.50	0.41	0.04	0.40	0.32	0.51	0.00	0.03	0.00	-0.07	0.10
Omalizumab 300mg	68	0.40	0.04	0.39	0.33	0.51	0.40	0.04	0.40	0.33	0.51	0.00	0.03	0.01	-0.07	0.07
Early Term																
Placebo	10	0.40	0.04	0.41	0.34	0.45	0.42	0.03	0.43	0.34	0.45	0.02	0.02	0.02	0.00	0.05
Omalizumab 75mg	6	0.42	0.05	0.40	0.38	0.50	0.44	0.05	0.44	0.39	0.52	0.02	0.03	0.03	-0.03	0.06
Omalizumab 150mg	12	0.41	0.04	0.41	0.36	0.49	0.41	0.05	0.40	0.34	0.53	0.00	0.03	0.00	-0.05	0.05
Omalizumab 300mg	8	0.39	0.04	0.39	0.35	0.44	0.41	0.03	0.41	0.35	0.44	0.01	0.02	0.01	-0.01	0.05

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	137.81	15.41	140.00	106.00	177.00	137.81	15.41	140.00	106.00	177.00					
Omalizumab 75mg	70	135.77	12.47	135.00	102.00	169.00	135.77	12.47	135.00	102.00	169.00					
Omalizumab 150mg	86	136.85	13.27	135.00	103.00	171.00	136.85	13.27	135.00	103.00	171.00					
Omalizumab 300mg	81	133.28	13.52	133.00	102.00	173.00	133.28	13.52	133.00	102.00	173.00					
Week 4																
Placebo	72	138.03	15.28	139.50	106.00	177.00	136.89	13.89	138.00	107.00	169.00	-1.14	8.32	-0.50	-36.00	25.00
Omalizumab 75mg	66	135.36	11.97	134.50	102.00	167.00	134.53	11.94	135.00	100.00	165.00	-0.83	6.60	-1.50	-15.00	20.00
Omalizumab 150mg	83	136.77	13.50	135.00	103.00	171.00	135.49	12.14	137.00	96.00	167.00	-1.28	7.19	-1.00	-25.00	16.00
Omalizumab 300mg	76	133.83	13.34	133.00	102.00	173.00	133.83	12.28	133.00	101.00	161.00	0.00	6.54	0.00	-15.00	21.00
Week 8																
Placebo	65	137.55	14.88	138.00	106.00	177.00	136.83	12.21	138.00	105.00	167.00	-0.72	9.02	-1.00	-29.00	28.00
Omalizumab 75mg	62	135.37	11.99	134.50	102.00	167.00	134.71	10.97	134.00	106.00	160.00	-0.66	7.17	-0.50	-19.00	15.00
Omalizumab 150mg	76	136.58	13.09	135.00	103.00	166.00	135.63	12.31	135.00	103.00	162.00	-0.95	7.77	-1.00	-25.00	29.00
Omalizumab 300mg	73	133.88	13.54	133.00	102.00	173.00	133.88	13.18	135.00	103.00	170.00	0.00	7.33	0.00	-17.00	27.00
Week 12																
Placebo	64	137.59	15.24	138.00	106.00	177.00	137.92	13.71	141.00	108.00	173.00	0.33	7.54	-1.00	-15.00	26.00
Omalizumab 75mg	61	135.31	12.08	134.00	102.00	167.00	135.67	10.89	133.00	104.00	168.00	0.36	6.66	1.00	-18.00	17.00
Omalizumab 150mg	75	137.05	13.64	135.00	103.00	171.00	137.12	13.80	138.00	99.00	169.00	0.07	9.10	0.00	-34.00	32.00
Omalizumab 300mg	69	134.20	13.80	134.00	102.00	173.00	135.96	13.76	138.00	103.00	174.00	1.75	6.85	2.00	-15.00	18.00
Week 16																
Placebo	61	138.34	15.68	141.00	106.00	177.00	137.33	13.81	139.00	109.00	165.00	-1.02	8.39	-2.00	-26.00	24.00
Omalizumab 75mg	59	135.20	11.74	134.00	102.00	167.00	134.27	12.01	134.00	99.00	169.00	-0.93	5.85	0.00	-18.00	11.00
Omalizumab 150mg	69	136.49	13.67	135.00	103.00	171.00	136.39	12.74	136.00	110.00	170.00	-0.10	8.34	0.00	-20.00	32.00
Omalizumab 300mg	73	133.85	13.60	133.00	102.00	173.00	133.96	13.43	134.00	101.00	166.00	0.11	7.30	0.00	-20.00	14.00
Week 20																
Placebo	59	138.53	15.43	141.00	106.00	177.00	137.39	13.03	139.00	109.00	174.00	-1.14	9.16	0.00	-30.00	25.00
Omalizumab 75mg	60	134.95	11.81	134.00	102.00	167.00	134.95	12.00	134.00	106.00	170.00	0.00	5.87	0.50	-13.00	11.00
Omalizumab 150mg	68	137.35	13.35	135.00	103.00	171.00	138.69	12.32	137.00	113.00	173.00	1.34	7.65	0.00	-14.00	30.00
Omalizumab 300mg	72	133.68	13.62	133.00	102.00	173.00	133.25	13.39	134.50	95.00	167.00	-0.43	7.11	0.00	-23.00	18.00

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	138.26	15.44	141.00	106.00	177.00	136.65	13.10	140.00	109.00	166.00	-1.62	8.14	-2.00	-27.00	25.00
Omalizumab 75mg	64	135.00	12.03	134.50	102.00	167.00	136.25	12.36	137.00	107.00	169.00	1.25	6.56	0.50	-12.00	16.00
Omalizumab 150mg	76	136.62	13.48	135.00	103.00	171.00	136.88	12.88	137.00	109.00	169.00	0.26	8.41	0.00	-19.00	27.00
Omalizumab 300mg	73	132.81	12.77	133.00	102.00	172.00	135.58	13.17	134.00	106.00	166.00	2.77	6.77	3.00	-12.00	22.00
Week 32																
Placebo	62	138.66	15.50	141.00	106.00	177.00	136.52	14.71	140.50	103.00	166.00	-2.15	10.40	-2.00	-46.00	25.00
Omalizumab 75mg	56	135.29	11.26	134.00	113.00	167.00	135.86	11.42	134.50	114.00	168.00	0.57	7.77	0.50	-16.00	28.00
Omalizumab 150mg	71	136.59	13.29	135.00	103.00	171.00	135.86	14.64	135.00	106.00	172.00	-0.73	8.68	-2.00	-22.00	23.00
Omalizumab 300mg	65	133.80	13.69	133.00	102.00	173.00	133.38	12.69	133.00	97.00	165.00	-0.42	7.22	0.00	-15.00	19.00
Week 40																
Placebo	62	138.69	15.46	141.00	106.00	177.00	140.11	13.36	141.50	114.00	166.00	1.42	9.11	2.00	-31.00	25.00
Omalizumab 75mg	55	136.20	11.72	136.00	113.00	167.00	136.56	11.24	135.00	114.00	167.00	0.36	6.68	0.00	-14.00	17.00
Omalizumab 150mg	69	136.57	13.14	135.00	103.00	171.00	136.70	13.72	135.00	107.00	172.00	0.13	8.45	0.00	-15.00	31.00
Omalizumab 300mg	68	133.74	13.64	133.00	102.00	173.00	134.49	12.63	134.00	106.00	164.00	0.75	7.90	1.00	-18.00	22.00
Early Term																
Placebo	10	137.10	15.57	137.00	114.00	158.00	144.50	12.39	146.50	118.00	160.00	7.40	7.03	4.50	-1.00	17.00
Omalizumab 75mg	6	142.33	16.42	137.00	128.00	169.00	146.67	15.51	139.50	133.00	174.00	4.33	3.88	5.00	-1.00	10.00
Omalizumab 150mg	12	138.00	14.34	134.50	118.00	166.00	138.50	13.12	137.00	123.00	171.00	0.50	7.38	1.00	-16.00	11.00
Omalizumab 300mg	8	131.50	15.28	134.50	108.00	150.00	136.75	15.19	137.50	107.00	158.00	5.25	9.77	2.50	-4.00	22.00

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.27	0.09	0.27	0.08	0.46	0.27	0.09	0.27	0.08	0.46					
Omalizumab 75mg	70	0.30	0.10	0.28	0.05	0.58	0.30	0.10	0.28	0.05	0.58					
Omalizumab 150mg	86	0.29	0.08	0.29	0.07	0.51	0.29	0.08	0.29	0.07	0.51					
Omalizumab 300mg	81	0.29	0.09	0.28	0.10	0.53	0.29	0.09	0.28	0.10	0.53					
Week 4																
Placebo	72	0.28	0.08	0.28	0.12	0.46	0.31	0.08	0.30	0.13	0.53	0.03	0.04	0.02	-0.11	0.15
Omalizumab 75mg	66	0.30	0.09	0.29	0.12	0.58	0.30	0.08	0.29	0.07	0.50	-0.00	0.07	0.00	-0.22	0.17
Omalizumab 150mg	83	0.29	0.08	0.29	0.07	0.51	0.30	0.07	0.29	0.15	0.49	0.01	0.06	0.01	-0.11	0.22
Omalizumab 300mg	76	0.29	0.08	0.28	0.10	0.53	0.31	0.07	0.30	0.15	0.52	0.02	0.08	0.02	-0.20	0.22
Week 8																
Placebo	65	0.28	0.08	0.28	0.12	0.46	0.28	0.08	0.28	0.12	0.47	0.00	0.07	0.00	-0.13	0.27
Omalizumab 75mg	62	0.30	0.09	0.29	0.12	0.58	0.29	0.08	0.28	0.12	0.44	-0.01	0.07	-0.00	-0.19	0.15
Omalizumab 150mg	76	0.29	0.08	0.29	0.07	0.51	0.31	0.08	0.31	0.13	0.50	0.02	0.07	0.02	-0.15	0.20
Omalizumab 300mg	73	0.29	0.09	0.28	0.10	0.53	0.30	0.08	0.29	0.13	0.48	0.01	0.09	0.02	-0.17	0.29
Week 12																
Placebo	64	0.28	0.08	0.27	0.12	0.46	0.28	0.09	0.28	0.11	0.49	0.01	0.07	0.01	-0.17	0.32
Omalizumab 75mg	61	0.30	0.09	0.29	0.12	0.58	0.30	0.08	0.30	0.16	0.53	0.00	0.07	0.01	-0.21	0.17
Omalizumab 150mg	75	0.28	0.08	0.28	0.07	0.51	0.30	0.08	0.30	0.16	0.53	0.02	0.07	0.01	-0.17	0.24
Omalizumab 300mg	69	0.29	0.09	0.28	0.10	0.53	0.31	0.08	0.30	0.15	0.56	0.02	0.07	0.01	-0.13	0.29
Week 16																
Placebo	61	0.28	0.08	0.27	0.12	0.46	0.30	0.08	0.29	0.15	0.51	0.03	0.06	0.03	-0.13	0.30
Omalizumab 75mg	59	0.30	0.09	0.29	0.12	0.58	0.30	0.07	0.29	0.16	0.45	-0.00	0.09	0.02	-0.27	0.18
Omalizumab 150mg	69	0.29	0.08	0.29	0.07	0.51	0.31	0.08	0.32	0.17	0.53	0.02	0.06	0.03	-0.15	0.21
Omalizumab 300mg	73	0.29	0.09	0.28	0.10	0.53	0.30	0.07	0.30	0.16	0.52	0.01	0.08	0.02	-0.25	0.28
Week 20																
Placebo	59	0.28	0.08	0.27	0.12	0.46	0.31	0.08	0.31	0.14	0.50	0.03	0.07	0.03	-0.07	0.30
Omalizumab 75mg	60	0.31	0.09	0.29	0.12	0.58	0.32	0.09	0.31	0.16	0.54	0.01	0.07	0.01	-0.15	0.17
Omalizumab 150mg	68	0.29	0.08	0.28	0.07	0.51	0.32	0.09	0.31	0.14	0.59	0.03	0.09	0.02	-0.15	0.23
Omalizumab 300mg	72	0.29	0.09	0.28	0.10	0.53	0.31	0.08	0.30	0.16	0.53	0.02	0.08	0.01	-0.13	0.23

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.28	0.08	0.27	0.12	0.46	0.29	0.08	0.29	0.07	0.48	0.02	0.08	0.02	-0.30	0.32
Omalizumab 75mg	64	0.31	0.09	0.30	0.12	0.58	0.30	0.09	0.29	0.16	0.54	-0.01	0.08	-0.01	-0.22	0.17
Omalizumab 150mg	76	0.30	0.08	0.29	0.14	0.51	0.31	0.08	0.30	0.17	0.50	0.01	0.07	0.02	-0.19	0.17
Omalizumab 300mg	73	0.29	0.08	0.28	0.10	0.53	0.30	0.07	0.29	0.10	0.47	0.01	0.08	0.00	-0.22	0.28
Week 32																
Placebo	62	0.28	0.08	0.27	0.12	0.46	0.30	0.09	0.29	0.10	0.51	0.02	0.07	0.03	-0.25	0.27
Omalizumab 75mg	56	0.31	0.09	0.30	0.12	0.58	0.29	0.07	0.28	0.13	0.43	-0.02	0.09	-0.00	-0.32	0.15
Omalizumab 150mg	71	0.29	0.08	0.29	0.14	0.51	0.30	0.10	0.30	0.08	0.51	0.01	0.07	0.01	-0.22	0.18
Omalizumab 300mg	65	0.29	0.08	0.28	0.10	0.47	0.30	0.08	0.30	0.06	0.47	0.01	0.07	0.00	-0.32	0.21
Week 40																
Placebo	62	0.27	0.08	0.27	0.12	0.46	0.30	0.08	0.29	0.14	0.50	0.02	0.07	0.02	-0.17	0.30
Omalizumab 75mg	55	0.30	0.09	0.30	0.12	0.54	0.30	0.09	0.30	0.12	0.52	-0.01	0.07	0.00	-0.21	0.17
Omalizumab 150mg	69	0.30	0.08	0.29	0.14	0.51	0.29	0.08	0.28	0.09	0.51	-0.00	0.07	-0.01	-0.28	0.20
Omalizumab 300mg	68	0.29	0.08	0.28	0.10	0.53	0.29	0.08	0.29	0.08	0.45	0.00	0.07	-0.00	-0.16	0.18
Early Term																
Placebo	10	0.25	0.08	0.24	0.12	0.38	0.28	0.10	0.26	0.15	0.46	0.03	0.06	0.04	-0.06	0.13
Omalizumab 75mg	6	0.21	0.09	0.24	0.05	0.30	0.21	0.08	0.21	0.09	0.34	-0.00	0.09	0.01	-0.15	0.09
Omalizumab 150mg	12	0.26	0.08	0.27	0.07	0.36	0.29	0.06	0.28	0.19	0.38	0.02	0.08	-0.00	-0.10	0.24
Omalizumab 300mg	8	0.26	0.11	0.28	0.13	0.42	0.28	0.10	0.26	0.11	0.43	0.02	0.11	-0.02	-0.12	0.19

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	2.06	0.72	1.97	0.84	4.66	2.06	0.72	1.97	0.84	4.66					
Omalizumab 75mg	70	2.01	0.57	1.95	0.76	3.54	2.01	0.57	1.95	0.76	3.54					
Omalizumab 150mg	86	2.04	0.67	1.98	0.41	5.51	2.04	0.67	1.98	0.41	5.51					
Omalizumab 300mg	81	2.00	0.60	1.95	0.77	3.36	2.00	0.60	1.95	0.77	3.36					
Week 4																
Placebo	72	2.10	0.71	2.02	0.84	4.66	2.19	0.67	2.12	0.85	4.60	0.10	0.45	0.08	-1.03	1.30
Omalizumab 75mg	66	2.01	0.54	1.95	1.02	3.54	1.96	0.54	1.83	0.88	3.55	-0.06	0.38	-0.03	-1.03	1.38
Omalizumab 150mg	83	2.02	0.64	1.97	0.41	5.51	2.00	0.56	1.84	1.18	3.65	-0.02	0.53	0.05	-3.03	0.79
Omalizumab 300mg	76	2.02	0.61	1.98	0.77	3.36	2.11	0.57	1.99	0.99	3.60	0.08	0.48	0.03	-1.10	2.21
Week 8																
Placebo	65	2.10	0.72	2.01	0.84	4.66	2.17	0.76	1.93	0.96	4.63	0.07	0.45	0.03	-0.83	1.95
Omalizumab 75mg	62	2.02	0.55	1.93	1.02	3.54	2.01	0.65	1.91	0.70	3.93	-0.01	0.47	-0.02	-1.06	1.24
Omalizumab 150mg	76	2.02	0.69	1.94	0.41	5.51	2.09	0.58	2.02	1.08	3.87	0.07	0.49	0.10	-1.64	1.32
Omalizumab 300mg	73	2.03	0.62	1.97	0.77	3.36	2.15	0.63	2.05	0.99	3.74	0.12	0.52	0.04	-1.09	2.22
Week 12																
Placebo	64	2.08	0.73	2.02	0.84	4.66	2.09	0.71	1.99	0.86	4.65	0.01	0.47	-0.00	-1.20	1.32
Omalizumab 75mg	61	2.03	0.55	1.94	1.02	3.54	1.96	0.53	1.89	1.03	3.40	-0.07	0.37	-0.05	-1.07	0.85
Omalizumab 150mg	75	2.03	0.69	1.97	0.41	5.51	2.02	0.60	1.88	1.10	4.74	-0.01	0.64	0.05	-3.30	2.27
Omalizumab 300mg	69	2.02	0.63	1.97	0.77	3.36	2.06	0.67	1.89	0.82	3.88	0.04	0.49	-0.09	-0.73	2.28
Week 16																
Placebo	61	2.09	0.74	2.01	0.84	4.66	2.24	0.67	2.12	0.92	4.51	0.14	0.49	0.13	-1.12	1.60
Omalizumab 75mg	59	2.06	0.54	1.96	1.06	3.54	2.06	0.56	1.99	1.19	3.64	0.00	0.48	-0.01	-1.25	0.90
Omalizumab 150mg	69	2.05	0.71	2.02	0.41	5.51	2.13	0.66	2.03	0.99	4.20	0.07	0.57	0.12	-1.57	1.73
Omalizumab 300mg	73	2.04	0.62	1.99	0.77	3.36	2.18	0.67	2.07	0.66	3.80	0.14	0.57	0.11	-1.01	2.56
Week 20																
Placebo	59	2.10	0.75	2.01	0.84	4.66	2.29	0.73	2.14	1.06	4.71	0.19	0.49	0.21	-1.29	1.52
Omalizumab 75mg	60	2.08	0.54	1.96	1.06	3.54	2.11	0.65	1.97	1.03	4.50	0.04	0.46	0.02	-1.11	1.57
Omalizumab 150mg	68	2.03	0.70	1.98	0.41	5.51	2.20	0.75	2.00	0.85	4.63	0.17	0.74	0.19	-3.02	1.97
Omalizumab 300mg	72	2.04	0.62	1.99	0.77	3.36	2.15	0.73	2.06	0.74	4.31	0.10	0.57	0.02	-1.27	3.07

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	2.09	0.67	2.02	1.01	4.66	2.15	0.63	2.01	1.15	4.32	0.06	0.53	-0.03	-1.37	1.72
Omalizumab 75mg	64	2.07	0.54	1.96	1.06	3.54	2.00	0.61	1.85	1.20	4.16	-0.07	0.42	-0.06	-1.01	0.93
Omalizumab 150mg	76	2.10	0.66	2.12	1.09	5.51	2.04	0.60	1.94	0.89	3.46	-0.05	0.67	-0.05	-3.89	1.08
Omalizumab 300mg	73	2.03	0.60	1.98	0.77	3.36	2.05	0.64	2.00	1.05	4.20	0.02	0.52	-0.01	-1.01	2.96
Week 32																
Placebo	62	2.10	0.67	2.03	1.01	4.66	2.29	0.80	2.19	0.93	4.76	0.20	0.59	0.08	-0.89	2.02
Omalizumab 75mg	56	2.07	0.55	1.96	1.06	3.54	2.05	0.58	1.97	0.72	3.19	-0.02	0.45	-0.04	-1.07	1.38
Omalizumab 150mg	71	2.10	0.68	2.14	1.09	5.51	2.15	0.70	1.95	1.07	5.31	0.06	0.60	0.01	-1.75	1.94
Omalizumab 300mg	65	2.05	0.63	1.99	0.77	3.36	2.25	0.84	2.12	1.10	5.99	0.20	0.75	0.17	-1.34	4.75
Week 40																
Placebo	62	2.08	0.68	2.02	1.01	4.66	2.11	0.68	1.93	1.08	4.51	0.03	0.54	0.03	-1.42	1.09
Omalizumab 75mg	55	2.07	0.56	1.96	1.06	3.54	2.04	0.63	1.93	0.88	3.83	-0.03	0.46	-0.02	-1.59	1.03
Omalizumab 150mg	69	2.04	0.55	1.99	1.09	3.89	1.93	0.59	1.81	1.00	4.20	-0.10	0.52	-0.05	-1.44	1.08
Omalizumab 300mg	68	2.06	0.61	2.00	0.77	3.36	2.15	0.76	2.02	0.63	5.72	0.10	0.77	0.04	-1.45	3.29
Early Term																
Placebo	10	1.75	0.67	1.74	0.84	3.30	2.03	0.85	1.91	0.67	4.07	0.27	0.40	0.28	-0.24	0.83
Omalizumab 75mg	6	1.53	0.72	1.39	0.76	2.81	1.55	0.48	1.44	1.02	2.44	0.01	0.29	-0.03	-0.37	0.43
Omalizumab 150mg	12	2.12	1.21	2.01	0.41	5.51	2.00	0.51	2.02	1.23	2.90	-0.11	1.06	0.10	-3.29	0.82
Omalizumab 300mg	8	1.72	0.49	1.64	1.35	2.87	2.26	1.08	1.76	1.08	4.18	0.54	1.04	0.17	-0.31	2.83

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.05	0.02	0.05	0.01	0.14	0.05	0.02	0.05	0.01	0.14					
Omalizumab 75mg	70	0.05	0.02	0.05	0.02	0.11	0.05	0.02	0.05	0.02	0.11					
Omalizumab 150mg	86	0.05	0.02	0.05	0.02	0.12	0.05	0.02	0.05	0.02	0.12					
Omalizumab 300mg	81	0.05	0.02	0.06	0.02	0.11	0.05	0.02	0.06	0.02	0.11					
Week 4																
Placebo	72	0.05	0.02	0.05	0.01	0.14	0.06	0.02	0.06	0.02	0.13	0.00	0.02	0.01	-0.08	0.05
Omalizumab 75mg	66	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.05	0.03	0.13	0.00	0.02	0.01	-0.02	0.05
Omalizumab 150mg	83	0.05	0.02	0.05	0.02	0.12	0.05	0.02	0.05	0.02	0.13	-0.00	0.02	0.00	-0.08	0.02
Omalizumab 300mg	76	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.06	0.02	0.12	0.00	0.02	0.00	-0.07	0.05
Week 8																
Placebo	65	0.05	0.02	0.05	0.01	0.14	0.05	0.02	0.05	0.02	0.13	0.00	0.02	-0.00	-0.09	0.06
Omalizumab 75mg	62	0.05	0.02	0.05	0.02	0.11	0.05	0.02	0.05	0.02	0.09	0.00	0.02	0.00	-0.04	0.05
Omalizumab 150mg	76	0.05	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.02	0.12	0.00	0.02	0.00	-0.06	0.03
Omalizumab 300mg	73	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.06	0.02	0.10	0.00	0.02	0.00	-0.07	0.04
Week 12																
Placebo	64	0.05	0.02	0.05	0.01	0.14	0.05	0.02	0.05	0.02	0.12	0.00	0.02	-0.00	-0.07	0.05
Omalizumab 75mg	61	0.05	0.02	0.05	0.02	0.11	0.05	0.01	0.05	0.03	0.09	0.00	0.02	0.00	-0.03	0.04
Omalizumab 150mg	75	0.05	0.02	0.05	0.02	0.12	0.05	0.02	0.05	0.02	0.12	-0.00	0.02	0.00	-0.04	0.05
Omalizumab 300mg	69	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.05	0.02	0.13	0.00	0.02	-0.00	-0.06	0.08
Week 16																
Placebo	61	0.05	0.02	0.05	0.01	0.14	0.05	0.02	0.05	0.02	0.11	0.00	0.02	0.00	-0.06	0.07
Omalizumab 75mg	59	0.05	0.01	0.05	0.02	0.09	0.05	0.01	0.05	0.02	0.10	0.00	0.02	0.01	-0.04	0.04
Omalizumab 150mg	69	0.05	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.03	0.13	0.00	0.01	0.00	-0.03	0.04
Omalizumab 300mg	73	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.06	0.02	0.12	0.01	0.02	0.01	-0.05	0.06
Week 20																
Placebo	59	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.06	0.02	0.16	0.01	0.02	0.01	-0.03	0.08
Omalizumab 75mg	60	0.05	0.02	0.05	0.02	0.11	0.05	0.02	0.05	0.03	0.10	0.00	0.02	0.00	-0.03	0.04
Omalizumab 150mg	68	0.06	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.02	0.12	0.00	0.02	0.00	-0.06	0.04
Omalizumab 300mg	72	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.06	0.03	0.14	0.01	0.02	0.00	-0.05	0.09

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.05	0.02	0.05	0.01	0.14	0.05	0.02	0.05	0.02	0.10	0.00	0.02	0.00	-0.08	0.06
Omalizumab 75mg	64	0.05	0.02	0.05	0.02	0.11	0.05	0.02	0.05	0.02	0.15	0.00	0.02	0.00	-0.07	0.10
Omalizumab 150mg	76	0.06	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.02	0.15	-0.00	0.02	0.00	-0.09	0.04
Omalizumab 300mg	73	0.05	0.02	0.06	0.02	0.11	0.06	0.02	0.05	0.03	0.12	0.00	0.02	0.00	-0.05	0.06
Week 32																
Placebo	62	0.05	0.02	0.05	0.01	0.14	0.06	0.02	0.06	0.02	0.13	0.01	0.02	0.01	-0.04	0.05
Omalizumab 75mg	56	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.05	0.02	0.11	0.00	0.02	0.00	-0.06	0.06
Omalizumab 150mg	71	0.06	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.03	0.13	0.00	0.02	0.00	-0.05	0.06
Omalizumab 300mg	65	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.05	0.02	0.15	0.00	0.02	0.00	-0.05	0.08
Week 40																
Placebo	62	0.05	0.02	0.05	0.01	0.14	0.06	0.02	0.06	0.03	0.13	0.00	0.02	0.00	-0.08	0.05
Omalizumab 75mg	55	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.05	0.02	0.11	0.00	0.02	0.00	-0.07	0.06
Omalizumab 150mg	69	0.06	0.02	0.05	0.02	0.12	0.06	0.02	0.05	0.02	0.13	-0.00	0.02	0.00	-0.05	0.04
Omalizumab 300mg	68	0.05	0.02	0.05	0.02	0.11	0.06	0.02	0.05	0.02	0.13	0.00	0.02	0.00	-0.04	0.09
Early Term																
Placebo	10	0.06	0.03	0.05	0.03	0.13	0.05	0.02	0.05	0.02	0.07	-0.01	0.03	0.00	-0.07	0.02
Omalizumab 75mg	6	0.05	0.03	0.04	0.03	0.11	0.04	0.02	0.03	0.03	0.09	-0.01	0.01	-0.01	-0.02	0.01
Omalizumab 150mg	12	0.05	0.02	0.05	0.02	0.08	0.06	0.03	0.05	0.03	0.12	0.01	0.02	0.01	-0.02	0.05
Omalizumab 300mg	8	0.05	0.02	0.06	0.03	0.07	0.06	0.02	0.05	0.03	0.10	0.00	0.02	0.00	-0.03	0.04

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.39	0.14	0.36	0.18	0.82	0.39	0.14	0.36	0.18	0.82					
Omalizumab 75mg	70	0.36	0.14	0.36	0.13	0.91	0.36	0.14	0.36	0.13	0.91					
Omalizumab 150mg	86	0.39	0.17	0.35	0.09	1.15	0.39	0.17	0.35	0.09	1.15					
Omalizumab 300mg	81	0.39	0.19	0.34	0.14	1.40	0.39	0.19	0.34	0.14	1.40					
Week 4																
Placebo	72	0.39	0.14	0.36	0.18	0.82	0.41	0.15	0.39	0.14	0.75	0.02	0.13	0.02	-0.38	0.34
Omalizumab 75mg	66	0.36	0.14	0.36	0.13	0.91	0.37	0.14	0.36	0.16	0.87	0.01	0.11	0.04	-0.27	0.22
Omalizumab 150mg	83	0.39	0.16	0.35	0.09	1.15	0.36	0.13	0.34	0.15	0.69	-0.03	0.13	-0.01	-0.56	0.21
Omalizumab 300mg	76	0.39	0.19	0.35	0.14	1.40	0.40	0.15	0.38	0.16	0.86	0.01	0.16	0.01	-0.62	0.48
Week 8																
Placebo	65	0.39	0.14	0.36	0.18	0.82	0.40	0.14	0.40	0.17	0.82	0.01	0.12	0.01	-0.24	0.33
Omalizumab 75mg	62	0.35	0.13	0.36	0.14	0.91	0.37	0.12	0.37	0.09	0.74	0.02	0.12	0.01	-0.30	0.41
Omalizumab 150mg	76	0.39	0.17	0.34	0.09	1.15	0.39	0.17	0.38	0.14	1.04	-0.00	0.17	0.00	-1.01	0.34
Omalizumab 300mg	73	0.39	0.19	0.34	0.14	1.40	0.41	0.14	0.40	0.20	0.92	0.02	0.17	0.03	-0.95	0.31
Week 12																
Placebo	64	0.39	0.14	0.37	0.18	0.82	0.39	0.13	0.37	0.19	0.92	-0.00	0.11	0.00	-0.23	0.25
Omalizumab 75mg	61	0.35	0.13	0.35	0.14	0.91	0.34	0.12	0.32	0.12	0.66	-0.00	0.13	0.00	-0.31	0.28
Omalizumab 150mg	75	0.39	0.17	0.34	0.09	1.15	0.38	0.20	0.35	0.05	1.35	-0.01	0.13	0.00	-0.39	0.47
Omalizumab 300mg	69	0.39	0.19	0.34	0.14	1.40	0.39	0.17	0.34	0.12	1.16	-0.01	0.15	-0.02	-0.51	0.40
Week 16																
Placebo	61	0.38	0.13	0.36	0.18	0.81	0.40	0.13	0.38	0.15	0.73	0.02	0.14	0.01	-0.35	0.37
Omalizumab 75mg	59	0.35	0.13	0.35	0.14	0.91	0.36	0.11	0.35	0.16	0.75	0.02	0.10	0.01	-0.17	0.29
Omalizumab 150mg	69	0.39	0.17	0.34	0.09	1.15	0.39	0.15	0.37	0.15	0.94	-0.00	0.12	-0.01	-0.25	0.35
Omalizumab 300mg	73	0.40	0.19	0.35	0.14	1.40	0.44	0.17	0.42	0.11	0.89	0.05	0.19	0.04	-0.76	0.49
Week 20																
Placebo	59	0.38	0.11	0.36	0.20	0.65	0.44	0.16	0.41	0.21	1.09	0.06	0.14	0.04	-0.15	0.67
Omalizumab 75mg	60	0.35	0.13	0.36	0.14	0.91	0.36	0.14	0.34	0.17	0.89	0.01	0.13	0.01	-0.29	0.51
Omalizumab 150mg	68	0.40	0.18	0.35	0.09	1.15	0.40	0.15	0.39	0.15	0.82	-0.00	0.16	-0.01	-0.69	0.38
Omalizumab 300mg	72	0.40	0.19	0.35	0.14	1.40	0.42	0.16	0.40	0.15	0.89	0.03	0.16	0.03	-0.51	0.45

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.38	0.13	0.36	0.18	0.81	0.39	0.13	0.36	0.17	0.71	0.01	0.15	0.01	-0.55	0.48
Omalizumab 75mg	64	0.35	0.14	0.36	0.13	0.91	0.36	0.17	0.34	0.14	1.32	0.01	0.18	0.02	-0.57	0.94
Omalizumab 150mg	76	0.40	0.17	0.35	0.12	1.15	0.38	0.15	0.37	0.10	0.87	-0.02	0.14	-0.00	-0.66	0.34
Omalizumab 300mg	73	0.39	0.19	0.34	0.14	1.40	0.40	0.14	0.37	0.17	0.79	0.01	0.15	0.02	-0.63	0.32
Week 32																
Placebo	62	0.38	0.13	0.37	0.18	0.81	0.44	0.14	0.44	0.20	0.86	0.06	0.15	0.06	-0.30	0.63
Omalizumab 75mg	56	0.37	0.14	0.36	0.14	0.91	0.40	0.18	0.37	0.13	1.16	0.04	0.16	0.01	-0.29	0.81
Omalizumab 150mg	71	0.40	0.17	0.35	0.12	1.15	0.43	0.22	0.39	0.17	1.35	0.03	0.18	0.00	-0.32	1.00
Omalizumab 300mg	65	0.39	0.20	0.35	0.14	1.40	0.42	0.19	0.38	0.18	1.23	0.03	0.19	0.03	-0.63	0.72
Week 40																
Placebo	62	0.38	0.13	0.37	0.18	0.81	0.40	0.14	0.38	0.12	0.93	0.01	0.14	-0.01	-0.44	0.43
Omalizumab 75mg	55	0.37	0.14	0.36	0.14	0.91	0.40	0.21	0.34	0.12	1.12	0.03	0.18	0.02	-0.33	0.74
Omalizumab 150mg	69	0.39	0.14	0.35	0.12	0.76	0.38	0.15	0.36	0.12	0.79	-0.01	0.12	-0.01	-0.33	0.29
Omalizumab 300mg	68	0.40	0.19	0.35	0.14	1.40	0.42	0.20	0.40	0.16	1.48	0.02	0.22	0.01	-0.42	1.24
Early Term																
Placebo	10	0.41	0.19	0.33	0.21	0.82	0.35	0.13	0.33	0.17	0.59	-0.06	0.25	-0.01	-0.65	0.30
Omalizumab 75mg	6	0.38	0.13	0.42	0.17	0.54	0.31	0.10	0.37	0.16	0.40	-0.07	0.14	-0.04	-0.34	0.06
Omalizumab 150mg	12	0.38	0.28	0.29	0.09	1.15	0.42	0.26	0.31	0.17	1.04	0.04	0.12	0.01	-0.11	0.33
Omalizumab 300mg	8	0.37	0.12	0.34	0.25	0.61	0.44	0.14	0.44	0.22	0.67	0.07	0.20	0.01	-0.17	0.37

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	0.64	0.09	0.65	0.45	0.87	0.64	0.09	0.65	0.45	0.87					
Omalizumab 75mg	70	0.62	0.11	0.63	0.27	0.92	0.62	0.11	0.63	0.27	0.92					
Omalizumab 150mg	86	0.62	0.09	0.63	0.34	0.91	0.62	0.09	0.63	0.34	0.91					
Omalizumab 300mg	81	0.63	0.10	0.64	0.34	0.83	0.63	0.10	0.64	0.34	0.83					
Week 4																
Placebo	72	0.64	0.09	0.65	0.45	0.81	0.61	0.09	0.61	0.39	0.78	-0.03	0.05	-0.02	-0.16	0.15
Omalizumab 75mg	66	0.61	0.10	0.62	0.27	0.83	0.61	0.09	0.63	0.37	0.86	0.00	0.08	-0.01	-0.20	0.24
Omalizumab 150mg	83	0.62	0.09	0.63	0.34	0.91	0.62	0.09	0.62	0.40	0.78	-0.01	0.06	-0.01	-0.26	0.16
Omalizumab 300mg	76	0.62	0.10	0.64	0.34	0.83	0.60	0.08	0.61	0.41	0.80	-0.02	0.09	-0.02	-0.25	0.22
Week 8																
Placebo	65	0.64	0.09	0.65	0.45	0.81	0.64	0.09	0.62	0.45	0.81	-0.00	0.09	0.00	-0.33	0.24
Omalizumab 75mg	62	0.61	0.10	0.63	0.27	0.83	0.62	0.08	0.62	0.45	0.79	0.01	0.08	0.01	-0.18	0.25
Omalizumab 150mg	76	0.62	0.09	0.63	0.42	0.91	0.61	0.09	0.59	0.39	0.81	-0.02	0.07	-0.01	-0.25	0.14
Omalizumab 300mg	73	0.62	0.10	0.64	0.34	0.83	0.60	0.09	0.60	0.42	0.79	-0.02	0.10	-0.02	-0.34	0.22
Week 12																
Placebo	64	0.64	0.09	0.65	0.45	0.81	0.63	0.10	0.64	0.43	0.86	-0.01	0.09	-0.00	-0.36	0.22
Omalizumab 75mg	61	0.61	0.10	0.62	0.27	0.83	0.61	0.09	0.62	0.40	0.81	-0.00	0.09	-0.01	-0.20	0.26
Omalizumab 150mg	75	0.63	0.09	0.63	0.42	0.91	0.61	0.08	0.62	0.39	0.78	-0.02	0.07	-0.01	-0.27	0.22
Omalizumab 300mg	69	0.62	0.10	0.64	0.34	0.83	0.60	0.09	0.60	0.29	0.78	-0.02	0.08	-0.01	-0.27	0.13
Week 16																
Placebo	61	0.64	0.09	0.66	0.45	0.81	0.61	0.08	0.61	0.41	0.80	-0.03	0.07	-0.03	-0.36	0.12
Omalizumab 75mg	59	0.61	0.10	0.63	0.27	0.83	0.62	0.08	0.61	0.43	0.80	0.00	0.10	-0.01	-0.19	0.30
Omalizumab 150mg	69	0.62	0.09	0.62	0.42	0.91	0.60	0.08	0.60	0.39	0.74	-0.02	0.07	-0.02	-0.26	0.16
Omalizumab 300mg	73	0.62	0.10	0.64	0.34	0.83	0.60	0.08	0.60	0.40	0.77	-0.02	0.09	-0.03	-0.23	0.25
Week 20																
Placebo	59	0.64	0.09	0.65	0.45	0.81	0.60	0.08	0.61	0.42	0.82	-0.04	0.08	-0.02	-0.35	0.09
Omalizumab 75mg	60	0.61	0.10	0.63	0.27	0.83	0.60	0.09	0.60	0.38	0.80	-0.01	0.08	-0.01	-0.21	0.18
Omalizumab 150mg	68	0.62	0.09	0.63	0.42	0.91	0.60	0.10	0.60	0.29	0.78	-0.03	0.10	-0.03	-0.27	0.16
Omalizumab 300mg	72	0.62	0.10	0.64	0.34	0.83	0.60	0.09	0.60	0.40	0.79	-0.02	0.09	-0.01	-0.27	0.13

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_hemato)
Database (CLOSED) Datasets (labv)
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Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	0.64	0.09	0.66	0.45	0.85	0.62	0.08	0.62	0.43	0.91	-0.02	0.09	-0.02	-0.38	0.33
Omalizumab 75mg	64	0.61	0.10	0.62	0.27	0.83	0.61	0.10	0.63	0.37	0.79	0.01	0.10	0.01	-0.22	0.25
Omalizumab 150mg	76	0.61	0.09	0.62	0.34	0.79	0.60	0.10	0.60	0.35	0.80	-0.01	0.08	-0.01	-0.19	0.18
Omalizumab 300mg	73	0.62	0.09	0.63	0.34	0.83	0.61	0.08	0.62	0.42	0.86	-0.01	0.09	-0.01	-0.24	0.28
Week 32																
Placebo	62	0.64	0.09	0.66	0.45	0.85	0.61	0.10	0.62	0.36	0.84	-0.03	0.08	-0.04	-0.32	0.20
Omalizumab 75mg	56	0.60	0.11	0.62	0.27	0.83	0.63	0.08	0.64	0.42	0.82	0.03	0.10	0.02	-0.19	0.39
Omalizumab 150mg	71	0.62	0.09	0.63	0.34	0.79	0.61	0.11	0.62	0.37	0.87	-0.01	0.08	-0.01	-0.18	0.29
Omalizumab 300mg	65	0.63	0.09	0.64	0.43	0.83	0.62	0.09	0.61	0.40	0.88	-0.01	0.09	0.01	-0.19	0.39
Week 40																
Placebo	62	0.64	0.09	0.66	0.45	0.85	0.62	0.09	0.62	0.42	0.80	-0.03	0.08	-0.02	-0.35	0.13
Omalizumab 75mg	55	0.61	0.10	0.62	0.36	0.83	0.62	0.09	0.61	0.43	0.84	0.01	0.09	0.01	-0.21	0.19
Omalizumab 150mg	69	0.61	0.09	0.62	0.34	0.79	0.62	0.10	0.63	0.35	0.86	0.00	0.09	0.01	-0.28	0.34
Omalizumab 300mg	68	0.63	0.09	0.64	0.34	0.83	0.63	0.09	0.63	0.39	0.85	-0.00	0.08	0.01	-0.20	0.17
Early Term																
Placebo	10	0.66	0.10	0.66	0.53	0.80	0.64	0.11	0.67	0.45	0.77	-0.02	0.08	-0.02	-0.14	0.09
Omalizumab 75mg	6	0.70	0.13	0.70	0.56	0.92	0.72	0.13	0.73	0.50	0.87	0.02	0.12	-0.01	-0.09	0.23
Omalizumab 150mg	12	0.67	0.10	0.64	0.55	0.91	0.64	0.06	0.62	0.56	0.76	-0.03	0.09	-0.00	-0.29	0.05
Omalizumab 300mg	8	0.65	0.13	0.60	0.46	0.82	0.63	0.10	0.63	0.49	0.84	-0.01	0.11	0.04	-0.21	0.10

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	5.14	1.99	4.79	1.84	11.83	5.14	1.99	4.79	1.84	11.83					
Omalizumab 75mg	70	4.60	2.16	4.65	0.93	13.77	4.60	2.16	4.65	0.93	13.77					
Omalizumab 150mg	86	4.60	1.62	4.50	1.84	9.29	4.60	1.62	4.50	1.84	9.29					
Omalizumab 300mg	81	4.73	1.87	4.55	1.20	9.44	4.73	1.87	4.55	1.20	9.44					
Week 4																
Placebo	72	5.01	1.84	4.77	1.84	11.83	4.59	1.84	4.35	1.84	11.02	-0.42	1.17	-0.44	-4.56	4.33
Omalizumab 75mg	66	4.39	1.65	4.64	0.93	10.91	4.24	1.59	3.87	1.31	10.24	-0.15	1.48	-0.07	-6.63	3.88
Omalizumab 150mg	83	4.59	1.65	4.48	1.84	9.29	4.35	1.53	4.15	1.54	8.54	-0.24	1.26	0.05	-5.18	2.27
Omalizumab 300mg	76	4.66	1.80	4.55	1.20	9.44	4.37	1.67	4.16	1.77	11.23	-0.29	1.47	-0.23	-3.50	5.38
Week 8																
Placebo	65	5.05	1.88	4.78	1.84	11.83	5.09	1.81	4.97	2.22	9.83	0.04	1.61	0.19	-6.16	5.17
Omalizumab 75mg	62	4.49	1.91	4.64	0.93	11.79	4.46	1.70	4.25	2.06	9.57	-0.03	1.45	-0.04	-6.44	2.58
Omalizumab 150mg	76	4.57	1.60	4.48	1.93	9.29	4.37	1.62	4.08	1.28	8.89	-0.20	1.43	-0.07	-5.34	3.46
Omalizumab 300mg	73	4.65	1.80	4.55	1.20	9.44	4.51	1.65	4.39	1.59	8.66	-0.14	1.62	-0.13	-3.78	4.97
Week 12																
Placebo	64	5.07	1.89	4.87	1.84	11.83	5.08	2.43	4.65	2.22	12.98	0.01	2.21	-0.23	-6.36	8.23
Omalizumab 75mg	61	4.45	1.90	4.61	0.93	11.79	4.19	1.75	3.80	1.64	12.42	-0.26	1.47	-0.27	-6.48	3.17
Omalizumab 150mg	75	4.64	1.59	4.51	1.93	9.29	4.29	1.53	4.24	1.58	9.72	-0.35	1.39	-0.16	-4.43	3.06
Omalizumab 300mg	69	4.67	1.85	4.63	1.20	9.44	4.14	1.34	4.12	1.51	7.88	-0.52	1.24	-0.30	-4.09	1.86
Week 16																
Placebo	61	5.14	1.88	4.94	1.84	11.83	4.80	1.91	4.40	1.62	12.06	-0.34	1.71	-0.33	-5.81	6.22
Omalizumab 75mg	59	4.54	1.89	4.66	0.93	11.79	4.42	1.66	4.09	1.91	11.24	-0.12	1.60	-0.26	-5.91	4.83
Omalizumab 150mg	69	4.55	1.59	4.47	1.93	9.29	4.16	1.35	3.76	1.87	7.24	-0.39	1.13	-0.20	-3.01	2.63
Omalizumab 300mg	73	4.69	1.83	4.63	1.20	9.44	4.46	1.58	4.19	1.86	8.97	-0.23	1.56	-0.28	-3.65	5.34
Week 20																
Placebo	59	4.98	1.78	4.78	1.84	11.83	4.65	1.94	4.28	2.12	11.51	-0.33	1.76	-0.40	-5.70	5.13
Omalizumab 75mg	60	4.50	1.90	4.64	0.93	11.79	4.23	1.68	3.97	1.04	9.92	-0.26	1.46	-0.21	-7.19	2.31
Omalizumab 150mg	68	4.59	1.62	4.48	1.93	9.29	4.37	1.83	3.78	1.66	9.14	-0.23	1.73	-0.22	-6.76	4.88
Omalizumab 300mg	72	4.71	1.83	4.64	1.20	9.44	4.37	1.64	4.04	1.08	9.31	-0.34	1.54	-0.09	-4.26	3.22

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	5.12	1.97	4.78	1.84	11.83	4.91	2.61	4.49	2.03	19.42	-0.22	2.60	-0.41	-6.44	15.17
Omalizumab 75mg	64	4.42	1.88	4.60	0.93	11.79	4.38	1.89	3.75	1.05	10.64	-0.04	1.75	-0.03	-6.12	3.81
Omalizumab 150mg	76	4.57	1.67	4.48	1.84	9.29	4.19	1.53	3.90	1.86	9.04	-0.38	1.33	-0.46	-3.99	4.58
Omalizumab 300mg	73	4.65	1.81	4.55	1.20	9.44	4.43	1.89	3.85	1.97	14.43	-0.22	1.78	-0.28	-3.97	10.01
Week 32																
Placebo	62	5.18	1.99	4.79	1.84	11.83	4.97	2.08	4.58	1.82	12.66	-0.21	1.73	-0.31	-5.93	5.34
Omalizumab 75mg	56	4.43	1.97	4.60	0.93	11.79	4.71	1.67	4.47	2.48	10.21	0.28	1.65	0.25	-5.26	5.43
Omalizumab 150mg	71	4.64	1.70	4.51	1.84	9.29	4.77	2.44	4.34	1.52	15.83	0.13	1.83	-0.19	-4.41	7.35
Omalizumab 300mg	65	4.73	1.77	4.63	1.20	9.44	5.18	2.91	4.86	1.40	20.21	0.45	2.57	0.08	-2.97	16.64
Week 40																
Placebo	62	5.20	1.99	4.87	1.84	11.83	4.62	1.82	4.37	1.79	10.27	-0.58	1.56	-0.40	-6.18	3.48
Omalizumab 75mg	55	4.45	1.93	4.58	2.02	11.79	4.49	1.78	4.12	1.85	9.44	0.04	1.66	0.19	-7.01	4.26
Omalizumab 150mg	69	4.41	1.51	4.46	1.84	8.88	4.34	1.79	4.24	1.37	12.14	-0.07	1.33	-0.02	-2.44	4.40
Omalizumab 300mg	68	4.78	1.75	4.64	1.26	9.44	4.99	2.32	4.35	1.54	13.57	0.21	1.65	0.03	-3.30	4.32
Early Term																
Placebo	10	4.84	1.41	5.05	2.75	6.57	4.68	1.49	4.59	2.27	7.37	-0.16	1.39	-0.43	-1.86	1.94
Omalizumab 75mg	6	6.24	4.00	5.27	2.18	13.77	6.59	4.12	5.38	2.14	12.86	0.35	3.99	0.31	-3.56	7.48
Omalizumab 150mg	12	5.22	1.90	4.68	3.05	9.29	4.81	2.22	4.68	2.52	10.59	-0.41	1.58	0.19	-3.35	1.30
Omalizumab 300mg	8	5.00	2.69	4.40	1.93	8.90	5.50	3.20	4.17	2.66	12.47	0.50	2.58	-0.04	-3.44	5.25

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	286.98	68.11	280.00	127.00	492.00	286.98	68.11	280.00	127.00	492.00					
Omalizumab 75mg	70	290.86	80.65	275.00	79.00	560.00	290.86	80.65	275.00	79.00	560.00					
Omalizumab 150mg	86	280.74	58.61	282.50	155.00	517.00	280.74	58.61	282.50	155.00	517.00					
Omalizumab 300mg	81	290.88	85.81	276.00	144.00	655.00	290.88	85.81	276.00	144.00	655.00					
Week 4																
Placebo	72	287.10	68.03	276.00	141.00	492.00	280.51	69.06	268.00	138.00	458.00	-6.58	39.55	-12.50	-96.00	112.00
Omalizumab 75mg	66	289.02	79.56	275.00	79.00	560.00	274.88	77.62	271.50	78.00	512.00	-14.14	34.28	-18.00	-81.00	65.00
Omalizumab 150mg	83	282.31	58.43	283.00	155.00	517.00	274.86	52.06	279.00	172.00	423.00	-7.46	35.81	-10.00	-94.00	95.00
Omalizumab 300mg	75	290.59	88.70	276.00	144.00	655.00	276.20	84.97	265.00	123.00	669.00	-14.39	40.37	-17.00	-138.00	128.00
Week 8																
Placebo	65	289.83	68.43	280.00	141.00	492.00	283.29	71.28	268.00	148.00	486.00	-6.54	33.97	-8.00	-81.00	90.00
Omalizumab 75mg	61	292.25	83.34	278.00	79.00	560.00	278.69	76.43	268.00	104.00	471.00	-13.56	37.35	-11.00	-89.00	68.00
Omalizumab 150mg	76	279.63	59.14	281.00	155.00	517.00	281.16	66.48	273.50	156.00	509.00	1.53	44.50	0.00	-104.00	168.00
Omalizumab 300mg	73	290.64	88.32	276.00	144.00	655.00	269.51	81.16	259.00	138.00	564.00	-21.14	38.79	-18.00	-129.00	65.00
Week 12																
Placebo	64	288.61	68.91	278.50	141.00	492.00	294.06	74.47	281.50	153.00	534.00	5.45	34.83	3.50	-61.00	91.00
Omalizumab 75mg	61	293.00	82.50	278.00	79.00	560.00	284.33	84.61	273.00	93.00	563.00	-8.67	37.82	-8.00	-106.00	87.00
Omalizumab 150mg	75	279.93	60.52	280.00	155.00	517.00	278.93	76.58	268.00	67.00	597.00	-1.00	54.94	-4.00	-177.00	181.00
Omalizumab 300mg	69	288.67	90.13	273.00	144.00	655.00	274.70	84.91	262.00	127.00	606.00	-13.97	43.70	-13.00	-181.00	93.00
Week 16																
Placebo	60	290.52	64.82	281.00	176.00	492.00	281.72	63.23	278.50	145.00	511.00	-8.80	43.74	-10.50	-104.00	80.00
Omalizumab 75mg	58	296.67	78.35	279.50	186.00	560.00	284.83	74.29	279.50	163.00	500.00	-11.84	39.89	-15.00	-83.00	90.00
Omalizumab 150mg	69	277.91	53.67	280.00	155.00	401.00	272.06	56.61	263.00	129.00	407.00	-5.86	45.63	-6.00	-126.00	115.00
Omalizumab 300mg	72	291.03	89.84	273.50	144.00	655.00	274.00	85.78	258.00	134.00	632.00	-17.03	45.24	-20.00	-121.00	91.00
Week 20																
Placebo	57	290.35	66.26	280.00	141.00	492.00	290.30	71.22	280.00	128.00	558.00	-0.05	41.18	-6.00	-92.00	106.00
Omalizumab 75mg	58	296.67	78.35	279.50	186.00	560.00	286.45	73.07	270.50	167.00	502.00	-10.22	47.93	-10.50	-124.00	94.00
Omalizumab 150mg	66	278.02	55.65	278.50	155.00	401.00	270.05	61.07	260.00	153.00	466.00	-7.97	50.65	-8.00	-112.00	136.00
Omalizumab 300mg	72	291.32	89.92	273.50	144.00	655.00	278.22	88.42	264.50	131.00	631.00	-13.10	51.08	-9.00	-138.00	128.00

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	291.63	68.63	282.00	141.00	492.00	292.74	80.81	274.00	149.00	555.00	1.11	51.03	3.00	-160.00	126.00
Omalizumab 75mg	62	294.42	76.44	276.50	186.00	560.00	292.19	75.29	280.00	164.00	506.00	-2.23	37.74	-1.50	-88.00	71.00
Omalizumab 150mg	76	281.41	58.37	283.00	155.00	517.00	279.30	61.45	280.50	140.00	477.00	-2.11	42.96	-8.50	-100.00	136.00
Omalizumab 300mg	73	295.97	86.36	276.00	157.00	655.00	290.56	81.76	280.00	139.00	578.00	-5.41	42.49	-1.00	-111.00	112.00
Week 32																
Placebo	61	295.11	67.75	283.00	141.00	492.00	291.62	72.40	293.00	163.00	544.00	-3.49	50.95	-4.00	-104.00	169.00
Omalizumab 75mg	55	286.35	67.68	275.00	186.00	476.00	293.20	64.12	298.00	169.00	484.00	6.85	41.66	4.00	-89.00	147.00
Omalizumab 150mg	71	280.27	59.69	282.00	155.00	517.00	278.38	62.36	275.00	155.00	433.00	-1.89	51.58	-6.00	-96.00	209.00
Omalizumab 300mg	65	292.31	92.87	274.00	144.00	655.00	294.25	97.56	275.00	123.00	641.00	1.94	50.92	-7.00	-123.00	140.00
Week 40																
Placebo	62	290.74	69.51	282.00	141.00	492.00	293.66	73.62	289.50	162.00	546.00	2.92	48.21	9.50	-94.00	142.00
Omalizumab 75mg	55	288.53	66.90	278.00	186.00	476.00	294.82	57.42	297.00	197.00	490.00	6.29	39.23	6.00	-81.00	88.00
Omalizumab 150mg	69	278.10	59.77	275.00	155.00	517.00	286.13	68.18	290.00	165.00	539.00	8.03	64.13	-2.00	-97.00	366.00
Omalizumab 300mg	68	292.53	91.63	273.50	144.00	655.00	305.01	96.64	278.00	151.00	637.00	12.49	55.64	11.00	-130.00	166.00
Early Term																
Placebo	10	271.30	58.34	261.00	199.00	402.00	277.40	70.65	249.00	211.00	443.00	6.10	29.36	12.50	-45.00	41.00
Omalizumab 75mg	6	267.00	136.24	257.00	79.00	466.00	270.33	158.44	242.50	104.00	543.00	3.33	42.31	-10.00	-32.00	77.00
Omalizumab 150mg	12	282.33	59.30	291.00	180.00	368.00	270.50	40.91	258.00	231.00	365.00	-11.83	53.64	-12.50	-82.00	96.00
Omalizumab 300mg	8	290.63	31.74	282.50	258.00	343.00	306.13	57.25	295.50	225.00	403.00	15.50	51.63	11.50	-42.00	80.00

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	4.74	0.49	4.75	3.50	6.60	4.74	0.49	4.75	3.50	6.60					
Omalizumab 75mg	70	4.64	0.41	4.60	3.90	5.60	4.64	0.41	4.60	3.90	5.60					
Omalizumab 150mg	86	4.66	0.44	4.60	3.90	5.80	4.66	0.44	4.60	3.90	5.80					
Omalizumab 300mg	81	4.55	0.42	4.60	3.50	5.50	4.55	0.42	4.60	3.50	5.50					
Week 4																
Placebo	72	4.73	0.50	4.70	3.50	6.60	4.70	0.47	4.70	3.80	6.70	-0.03	0.30	0.00	-1.20	0.90
Omalizumab 75mg	66	4.62	0.40	4.60	3.90	5.60	4.58	0.38	4.60	3.70	5.40	-0.04	0.24	-0.05	-0.60	0.50
Omalizumab 150mg	83	4.66	0.45	4.60	3.90	5.80	4.61	0.40	4.50	3.90	5.60	-0.05	0.25	0.00	-0.90	0.60
Omalizumab 300mg	76	4.57	0.41	4.60	3.50	5.50	4.58	0.37	4.60	3.60	5.30	0.01	0.24	0.00	-0.40	0.60
Week 8																
Placebo	65	4.73	0.49	4.70	3.50	6.60	4.70	0.47	4.60	3.80	7.00	-0.03	0.33	-0.10	-1.00	1.00
Omalizumab 75mg	62	4.61	0.40	4.60	3.90	5.60	4.58	0.37	4.60	3.80	5.30	-0.03	0.27	0.00	-0.70	0.70
Omalizumab 150mg	76	4.66	0.44	4.60	3.90	5.80	4.63	0.42	4.60	3.90	5.70	-0.02	0.29	0.00	-0.90	1.00
Omalizumab 300mg	73	4.57	0.41	4.60	3.50	5.50	4.58	0.40	4.70	3.40	5.20	0.01	0.28	0.00	-0.70	0.90
Week 12																
Placebo	64	4.73	0.50	4.70	3.50	6.60	4.76	0.48	4.70	3.80	6.80	0.03	0.28	0.00	-0.50	1.00
Omalizumab 75mg	61	4.61	0.41	4.60	3.90	5.60	4.62	0.35	4.60	4.00	5.50	0.01	0.25	0.00	-0.60	0.60
Omalizumab 150mg	75	4.66	0.45	4.60	3.90	5.80	4.66	0.46	4.60	3.10	5.70	0.00	0.31	0.00	-1.10	1.00
Omalizumab 300mg	69	4.58	0.42	4.60	3.50	5.50	4.63	0.38	4.60	3.70	5.30	0.06	0.24	0.10	-0.60	0.60
Week 16																
Placebo	61	4.77	0.50	4.80	3.50	6.60	4.73	0.52	4.70	3.80	6.90	-0.04	0.31	-0.10	-0.90	0.80
Omalizumab 75mg	59	4.63	0.39	4.60	4.00	5.60	4.59	0.39	4.60	3.90	5.60	-0.04	0.23	0.00	-0.60	0.40
Omalizumab 150mg	69	4.66	0.45	4.60	3.90	5.80	4.65	0.40	4.60	3.70	5.60	-0.01	0.27	0.00	-0.70	0.70
Omalizumab 300mg	73	4.58	0.41	4.60	3.50	5.50	4.58	0.41	4.60	3.80	5.60	0.01	0.25	0.00	-0.60	0.60
Week 20																
Placebo	59	4.76	0.50	4.80	3.50	6.60	4.72	0.48	4.70	3.90	6.60	-0.04	0.33	0.00	-1.10	0.90
Omalizumab 75mg	60	4.62	0.40	4.60	4.00	5.60	4.60	0.37	4.60	4.00	5.50	-0.02	0.23	0.00	-1.00	0.40
Omalizumab 150mg	68	4.66	0.45	4.60	3.90	5.80	4.67	0.42	4.70	4.00	5.90	0.01	0.24	0.00	-0.50	0.60
Omalizumab 300mg	72	4.57	0.42	4.60	3.50	5.50	4.55	0.43	4.60	3.60	5.80	-0.03	0.27	0.00	-0.90	0.60

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	4.77	0.50	4.80	3.50	6.60	4.70	0.46	4.70	3.80	6.70	-0.07	0.31	-0.10	-1.10	1.00
Omalizumab 75mg	64	4.63	0.41	4.60	3.90	5.60	4.64	0.40	4.70	3.90	5.40	0.01	0.23	0.00	-0.60	0.50
Omalizumab 150mg	76	4.66	0.44	4.60	3.90	5.80	4.66	0.44	4.60	4.00	5.80	-0.01	0.28	0.00	-0.60	0.70
Omalizumab 300mg	73	4.54	0.40	4.60	3.50	5.50	4.59	0.39	4.60	3.60	5.50	0.05	0.24	0.00	-0.50	0.60
Week 32																
Placebo	62	4.77	0.52	4.80	3.50	6.60	4.71	0.48	4.70	3.60	6.50	-0.06	0.26	-0.10	-0.60	1.00
Omalizumab 75mg	56	4.64	0.42	4.60	3.90	5.60	4.63	0.42	4.60	3.90	5.80	-0.01	0.28	0.00	-0.50	1.00
Omalizumab 150mg	71	4.67	0.44	4.60	3.90	5.80	4.63	0.45	4.60	3.70	5.80	-0.04	0.26	-0.10	-0.60	0.70
Omalizumab 300mg	65	4.56	0.44	4.60	3.50	5.50	4.54	0.40	4.60	3.50	5.30	-0.02	0.25	0.00	-0.70	0.60
Week 40																
Placebo	62	4.77	0.51	4.80	3.50	6.60	4.78	0.46	4.80	3.90	6.30	0.01	0.34	0.00	-1.10	1.00
Omalizumab 75mg	55	4.66	0.41	4.70	3.90	5.60	4.67	0.34	4.70	4.00	5.40	0.01	0.21	0.00	-0.40	0.50
Omalizumab 150mg	69	4.65	0.41	4.60	3.90	5.80	4.65	0.40	4.60	3.80	5.60	0.01	0.32	0.00	-0.90	0.80
Omalizumab 300mg	68	4.56	0.43	4.60	3.50	5.50	4.59	0.43	4.50	3.40	5.60	0.03	0.31	0.00	-0.80	0.90
Early Term																
Placebo	10	4.62	0.45	4.55	4.00	5.30	4.83	0.32	4.90	4.20	5.30	0.21	0.22	0.20	-0.10	0.50
Omalizumab 75mg	6	4.63	0.42	4.50	4.20	5.20	4.77	0.40	4.70	4.20	5.40	0.13	0.18	0.15	-0.10	0.40
Omalizumab 150mg	12	4.69	0.55	4.60	4.10	5.80	4.59	0.59	4.50	3.80	5.70	-0.10	0.16	-0.10	-0.40	0.30
Omalizumab 300mg	8	4.64	0.41	4.65	3.90	5.30	4.80	0.39	4.80	4.20	5.30	0.16	0.26	0.10	-0.10	0.60

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Baseline																
Placebo	80	7.82	2.22	7.44	4.05	15.05	7.82	2.22	7.44	4.05	15.05					
Omalizumab 75mg	70	7.22	2.29	7.01	3.32	15.16	7.22	2.29	7.01	3.32	15.16					
Omalizumab 150mg	86	7.27	1.99	7.15	3.25	15.24	7.27	1.99	7.15	3.25	15.24					
Omalizumab 300mg	81	7.35	2.23	7.37	2.44	13.10	7.35	2.23	7.37	2.44	13.10					
Week 4																
Placebo	72	7.74	2.14	7.32	4.05	15.05	7.41	2.22	6.86	3.67	14.08	-0.33	1.43	-0.51	-5.68	4.35
Omalizumab 75mg	66	7.01	1.89	7.01	3.32	13.16	6.77	1.79	6.49	3.11	11.93	-0.24	1.50	-0.06	-6.86	3.30
Omalizumab 150mg	83	7.23	2.00	7.15	3.25	15.24	6.92	1.85	6.96	3.08	11.50	-0.31	1.61	0.06	-8.32	2.93
Omalizumab 300mg	76	7.30	2.20	7.37	2.44	13.10	7.11	2.04	6.79	3.47	15.25	-0.19	1.57	-0.12	-3.82	5.87
Week 8																
Placebo	65	7.78	2.19	7.33	4.05	15.05	7.87	2.12	7.82	4.44	13.13	0.09	1.67	0.18	-5.25	4.96
Omalizumab 75mg	62	7.10	2.17	7.01	3.32	15.16	7.03	2.06	6.83	3.76	12.84	-0.07	1.50	0.08	-6.31	2.81
Omalizumab 150mg	76	7.21	1.99	7.05	3.25	15.24	7.09	1.92	6.87	3.19	11.46	-0.12	1.70	-0.10	-6.42	3.42
Omalizumab 300mg	73	7.31	2.21	7.37	2.44	13.10	7.30	1.94	7.12	3.45	11.30	-0.00	1.72	-0.05	-2.91	4.89
Week 12																
Placebo	64	7.79	2.20	7.44	4.05	15.05	7.78	2.64	7.46	4.22	16.60	-0.01	2.38	-0.46	-5.90	8.21
Omalizumab 75mg	61	7.07	2.17	7.00	3.32	15.16	6.71	2.06	6.61	3.22	15.40	-0.36	1.59	-0.52	-6.21	3.63
Omalizumab 150mg	75	7.30	1.97	7.15	3.25	15.24	6.94	1.96	6.79	3.11	12.99	-0.37	1.74	-0.19	-4.12	4.63
Omalizumab 300mg	69	7.32	2.27	7.37	2.44	13.10	6.82	1.75	6.46	2.71	11.04	-0.50	1.33	-0.30	-4.61	2.41
Week 16																
Placebo	61	7.85	2.18	7.54	4.05	15.05	7.67	2.28	7.09	4.01	15.32	-0.18	1.92	-0.14	-5.88	7.49
Omalizumab 75mg	59	7.20	2.14	7.01	3.32	15.16	7.05	1.99	6.66	3.38	14.06	-0.14	1.61	-0.28	-5.94	4.30
Omalizumab 150mg	69	7.24	2.01	7.15	3.25	15.24	6.89	1.76	7.05	3.60	11.17	-0.35	1.44	-0.21	-4.68	3.18
Omalizumab 300mg	73	7.35	2.22	7.37	2.44	13.10	7.29	1.98	7.02	3.22	12.56	-0.07	1.78	-0.12	-4.10	7.19
Week 20																
Placebo	59	7.70	2.12	7.25	4.05	15.05	7.60	2.31	7.04	3.99	14.18	-0.10	1.92	-0.01	-4.41	6.24
Omalizumab 75mg	60	7.17	2.14	7.01	3.32	15.16	6.91	2.10	6.49	2.77	14.28	-0.25	1.60	-0.32	-7.19	3.52
Omalizumab 150mg	68	7.27	2.03	7.15	3.25	15.24	7.18	2.23	6.84	3.82	13.10	-0.09	2.10	-0.13	-10.53	5.04
Omalizumab 300mg	72	7.38	2.23	7.40	2.44	13.10	7.17	2.16	6.84	2.50	12.68	-0.22	1.70	-0.11	-4.92	4.12

Table 14.3/28
Hematology Values by Visit
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

		Baseline					Value at Visit					Change from Baseline				
	n	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum	Mean	SD	Median	Minimum	Maximum
Week 24																
Placebo	65	7.83	2.18	7.33	4.05	15.05	7.69	2.89	7.30	3.90	21.34	-0.14	2.61	-0.19	-5.23	14.03
Omalizumab 75mg	64	7.09	2.12	6.96	3.32	15.16	6.96	2.26	6.77	2.86	13.44	-0.13	1.78	-0.19	-6.20	3.38
Omalizumab 150mg	76	7.31	2.07	7.17	3.25	15.24	6.84	1.76	6.86	3.47	11.63	-0.47	1.71	-0.42	-7.51	4.72
Omalizumab 300mg	73	7.30	2.23	7.37	2.44	13.10	7.08	2.22	6.62	3.97	16.81	-0.21	1.79	-0.19	-4.72	9.23
Week 32																
Placebo	62	7.90	2.20	7.44	4.05	15.05	7.94	2.40	7.80	4.14	15.07	0.05	2.04	-0.27	-4.97	6.70
Omalizumab 75mg	56	7.12	2.21	6.96	3.32	15.16	7.37	1.97	7.04	4.25	12.57	0.25	1.71	0.40	-4.86	5.66
Omalizumab 150mg	71	7.38	2.11	7.23	3.25	15.24	7.56	2.70	7.06	3.67	18.78	0.18	2.06	0.13	-4.51	7.71
Omalizumab 300mg	65	7.41	2.18	7.37	2.44	13.10	8.06	3.42	7.53	3.47	23.01	0.65	2.78	0.09	-3.10	15.72
Week 40																
Placebo	62	7.90	2.20	7.57	4.05	15.05	7.35	2.21	6.99	3.74	13.54	-0.55	1.82	-0.49	-5.29	4.87
Omalizumab 75mg	55	7.14	2.18	6.91	3.32	15.16	7.14	2.09	6.38	4.02	12.49	0.00	1.74	0.04	-6.83	4.44
Omalizumab 150mg	69	7.08	1.74	7.15	3.25	12.35	6.90	2.14	6.51	3.21	14.10	-0.18	1.55	-0.46	-3.24	3.71
Omalizumab 300mg	68	7.47	2.13	7.40	3.20	13.10	7.78	2.91	7.05	3.46	21.20	0.31	2.11	0.27	-3.98	8.58
Early Term																
Placebo	10	7.25	1.63	7.46	4.82	9.69	7.27	1.81	7.10	4.52	10.11	0.02	1.70	-0.09	-2.48	2.29
Omalizumab 75mg	6	8.40	3.81	8.23	3.89	15.02	8.64	4.40	7.37	4.30	15.87	0.24	3.72	0.49	-3.66	6.62
Omalizumab 150mg	12	7.87	3.00	6.58	5.23	15.24	7.36	2.73	7.44	4.05	13.96	-0.51	2.39	0.23	-6.86	1.76
Omalizumab 300mg	8	7.33	2.71	7.37	4.25	11.14	8.42	3.53	7.60	4.23	14.83	1.10	2.75	0.88	-2.98	5.33

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	4 (5.6%)	66 (93.0%)	0 (0.0%)	0 (0.0%)	70 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.6%)	67 (94.4%)	0 (0.0%)	0 (0.0%)	71 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
		Normal	0 (0.0%)	64 (97.0%)	0 (0.0%)	0 (0.0%)	64 (97.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	65 (98.5%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	2 (2.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Normal	0 (0.0%)	80 (96.4%)	0 (0.0%)	1 (1.2%)	81 (97.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.4%)	80 (96.4%)	0 (0.0%)	1 (1.2%)	83 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	1 (1.3%)	73 (97.3%)	0 (0.0%)	0 (0.0%)	74 (98.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	74 (98.7%)	0 (0.0%)	0 (0.0%)	75 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	5 (7.7%)	60 (92.3%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.7%)	60 (92.3%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	61 (98.4%)	0 (0.0%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	61 (98.4%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	3 (3.9%)
		Normal	1 (1.3%)	72 (93.5%)	0 (0.0%)	1 (1.3%)	74 (96.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	74 (96.1%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	3 (4.1%)	0 (0.0%)	0 (0.0%)	3 (4.1%)
		Normal	1 (1.4%)	69 (94.5%)	0 (0.0%)	0 (0.0%)	70 (95.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	72 (98.6%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	5 (8.2%)	55 (90.2%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.2%)	56 (91.8%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	60 (98.4%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (98.4%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	3 (4.1%)	0 (0.0%)	0 (0.0%)	3 (4.1%)
		Normal	2 (2.7%)	69 (93.2%)	0 (0.0%)	0 (0.0%)	71 (95.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	72 (97.3%)	0 (0.0%)	0 (0.0%)	74 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	66 (95.7%)	0 (0.0%)	0 (0.0%)	67 (97.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	68 (98.6%)	0 (0.0%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 16	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	5 (8.2%)	55 (90.2%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.2%)	56 (91.8%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	2 (3.4%)
		Normal	0 (0.0%)	57 (96.6%)	0 (0.0%)	0 (0.0%)	57 (96.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.9%)	64 (92.8%)	0 (0.0%)	1 (1.4%)	67 (97.1%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	66 (95.7%)	0 (0.0%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Normal	1 (1.4%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	70 (97.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	71 (98.6%)	0 (0.0%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 20	Placebo	Low	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	5 (8.5%)	53 (89.8%)	0 (0.0%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.5%)	54 (91.5%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	0 (0.0%)	59 (98.3%)	0 (0.0%)	0 (0.0%)	59 (98.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (100.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.9%)	65 (94.2%)	0 (0.0%)	1 (1.4%)	68 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	66 (95.7%)	0 (0.0%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	3 (4.2%)
		Normal	0 (0.0%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	69 (95.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	71 (98.6%)	0 (0.0%)	0 (0.0%)	72 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 24	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	5 (7.8%)	58 (90.6%)	0 (0.0%)	0 (0.0%)	63 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.8%)	59 (92.2%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	62 (98.4%)	0 (0.0%)	0 (0.0%)	62 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (100.0%)	0 (0.0%)	0 (0.0%)	63 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	1 (1.3%)	74 (96.1%)	0 (0.0%)	1 (1.3%)	76 (98.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	75 (97.4%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	1 (1.4%)	70 (95.9%)	0 (0.0%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	72 (98.6%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 32	Placebo	Low	1 (1.6%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
		Normal	4 (6.5%)	55 (88.7%)	0 (0.0%)	0 (0.0%)	59 (95.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (100.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (100.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.4%)	69 (97.2%)	0 (0.0%)	1 (1.4%)	71 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	69 (97.2%)	0 (0.0%)	1 (1.4%)	71 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	1 (1.6%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	62 (96.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	63 (98.4%)	0 (0.0%)	0 (0.0%)	64 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	5 (8.1%)	56 (90.3%)	0 (0.0%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	0 (0.0%)	54 (98.2%)	0 (0.0%)	0 (0.0%)	54 (98.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (100.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	66 (94.3%)	0 (0.0%)	1 (1.4%)	68 (97.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	68 (97.1%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	1 (1.5%)	65 (95.6%)	0 (0.0%)	0 (0.0%)	66 (97.1%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	67 (98.5%)	0 (0.0%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hematocrit (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Normal	0 (0.0%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (12.5%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	3 (4.2%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	5 (6.9%)
		Normal	2 (2.8%)	65 (90.3%)	0 (0.0%)	0 (0.0%)	67 (93.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.9%)	67 (93.1%)	0 (0.0%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	2 (3.0%)	3 (4.5%)	0 (0.0%)	0 (0.0%)	5 (7.6%)
		Normal	1 (1.5%)	60 (90.9%)	0 (0.0%)	0 (0.0%)	61 (92.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.5%)	63 (95.5%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	1 (1.2%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Normal	3 (3.6%)	78 (92.9%)	0 (0.0%)	1 (1.2%)	82 (97.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (4.8%)	79 (94.0%)	0 (0.0%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	5 (6.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.6%)
		Normal	0 (0.0%)	71 (93.4%)	0 (0.0%)	0 (0.0%)	71 (93.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.6%)	71 (93.4%)	0 (0.0%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	3 (4.6%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	4 (6.2%)
		Normal	2 (3.1%)	59 (90.8%)	0 (0.0%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.7%)	60 (92.3%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	2 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Normal	0 (0.0%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	2 (2.6%)	3 (3.9%)	0 (0.0%)	0 (0.0%)	5 (6.5%)
		Normal	2 (2.6%)	69 (89.6%)	0 (0.0%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.2%)	72 (93.5%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	5 (6.8%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	7 (9.6%)
		Normal	0 (0.0%)	66 (90.4%)	0 (0.0%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	68 (93.2%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 12	Placebo	Low	3 (4.7%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	4 (6.3%)
		Normal	2 (3.1%)	58 (90.6%)	0 (0.0%)	0 (0.0%)	60 (93.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.8%)	59 (92.2%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	59 (96.7%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	59 (96.7%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	4 (5.3%)	0 (0.0%)	0 (0.0%)	5 (6.7%)
		Normal	3 (4.0%)	67 (89.3%)	0 (0.0%)	0 (0.0%)	70 (93.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.3%)	71 (94.7%)	0 (0.0%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	4 (5.8%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	5 (7.2%)
		Normal	1 (1.4%)	63 (91.3%)	0 (0.0%)	0 (0.0%)	64 (92.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.2%)	64 (92.8%)	0 (0.0%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	3 (4.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (4.9%)
		Normal	2 (3.3%)	56 (91.8%)	0 (0.0%)	0 (0.0%)	58 (95.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.2%)	56 (91.8%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	2 (3.4%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	3 (5.1%)
		Normal	0 (0.0%)	56 (94.9%)	0 (0.0%)	0 (0.0%)	56 (94.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.4%)	57 (96.6%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	3 (4.3%)	63 (90.0%)	0 (0.0%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.7%)	65 (92.9%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	4 (5.5%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	6 (8.2%)
		Normal	1 (1.4%)	65 (89.0%)	0 (0.0%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	68 (93.2%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	2 (3.4%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	3 (5.1%)
		Normal	2 (3.4%)	54 (91.5%)	0 (0.0%)	0 (0.0%)	56 (94.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.8%)	55 (93.2%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	2 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	0 (0.0%)	58 (96.7%)	0 (0.0%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	58 (96.7%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	3 (4.3%)	64 (92.8%)	0 (0.0%)	1 (1.4%)	68 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	65 (94.2%)	0 (0.0%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	3 (4.2%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	5 (6.9%)
		Normal	2 (2.8%)	65 (90.3%)	0 (0.0%)	0 (0.0%)	67 (93.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.9%)	67 (93.1%)	0 (0.0%)	0 (0.0%)	72 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	3 (4.6%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	5 (7.7%)
		Normal	2 (3.1%)	58 (89.2%)	0 (0.0%)	0 (0.0%)	60 (92.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.7%)	60 (92.3%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	2 (3.1%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	4 (6.3%)
		Normal	1 (1.6%)	59 (92.2%)	0 (0.0%)	0 (0.0%)	60 (93.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	3 (3.9%)	0 (0.0%)	0 (0.0%)	4 (5.2%)
		Normal	2 (2.6%)	70 (90.9%)	0 (0.0%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.9%)	73 (94.8%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	4 (5.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (5.5%)
		Normal	1 (1.4%)	68 (93.2%)	0 (0.0%)	0 (0.0%)	69 (94.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	68 (93.2%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 32	Placebo	Low	3 (4.8%)	5 (8.1%)	0 (0.0%)	0 (0.0%)	8 (12.9%)
		Normal	2 (3.2%)	52 (83.9%)	0 (0.0%)	0 (0.0%)	54 (87.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
		Normal	1 (1.8%)	53 (94.6%)	0 (0.0%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	54 (96.4%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	3 (4.2%)	0 (0.0%)	0 (0.0%)	4 (5.6%)
		Normal	2 (2.8%)	65 (90.3%)	0 (0.0%)	1 (1.4%)	68 (94.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.2%)	68 (94.4%)	0 (0.0%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	3 (4.6%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	5 (7.7%)
		Normal	1 (1.5%)	59 (90.8%)	0 (0.0%)	0 (0.0%)	60 (92.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.2%)	61 (93.8%)	0 (0.0%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	2 (3.2%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
		Normal	3 (4.8%)	56 (90.3%)	0 (0.0%)	0 (0.0%)	59 (95.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
		Normal	1 (1.8%)	52 (94.5%)	0 (0.0%)	0 (0.0%)	53 (96.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	53 (96.4%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	2 (2.9%)	64 (91.4%)	0 (0.0%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	66 (94.3%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	3 (4.4%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	4 (5.9%)
		Normal	1 (1.5%)	62 (91.2%)	0 (0.0%)	0 (0.0%)	63 (92.6%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.9%)	64 (94.1%)	0 (0.0%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Hemoglobin (g/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (10.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (10.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Normal	1 (12.5%)	6 (75.0%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (25.0%)	6 (75.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	66 (91.7%)	0 (0.0%)	0 (0.0%)	66 (91.7%)
		High	0 (0.0%)	1 (1.4%)	4 (5.6%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (94.4%)	4 (5.6%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	0 (0.0%)	60 (90.9%)	2 (3.0%)	0 (0.0%)	62 (93.9%)
		High	0 (0.0%)	0 (0.0%)	3 (4.5%)	0 (0.0%)	3 (4.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	60 (90.9%)	5 (7.6%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	81 (96.4%)	1 (1.2%)	1 (1.2%)	83 (98.8%)
		High	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (1.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	81 (96.4%)	2 (2.4%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	0 (0.0%)	66 (88.0%)	4 (5.3%)	0 (0.0%)	70 (93.3%)
		High	0 (0.0%)	0 (0.0%)	3 (4.0%)	0 (0.0%)	3 (4.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (90.7%)	7 (9.3%)	0 (0.0%)	75 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (92.3%)	1 (1.5%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	1 (1.5%)	3 (4.6%)	0 (0.0%)	4 (6.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (93.8%)	4 (6.2%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	54 (88.5%)	2 (3.3%)	0 (0.0%)	56 (91.8%)
		High	0 (0.0%)	0 (0.0%)	4 (6.6%)	0 (0.0%)	4 (6.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	54 (88.5%)	6 (9.8%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	70 (90.9%)	1 (1.3%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	4 (5.2%)	1 (1.3%)	0 (0.0%)	5 (6.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	74 (96.1%)	2 (2.6%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	65 (89.0%)	4 (5.5%)	0 (0.0%)	69 (94.5%)
		High	0 (0.0%)	0 (0.0%)	3 (4.1%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	66 (90.4%)	7 (9.6%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (89.1%)	1 (1.6%)	0 (0.0%)	58 (90.6%)
		High	0 (0.0%)	3 (4.7%)	3 (4.7%)	0 (0.0%)	6 (9.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (93.8%)	4 (6.3%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	53 (86.9%)	2 (3.3%)	0 (0.0%)	55 (90.2%)
		High	0 (0.0%)	1 (1.6%)	4 (6.6%)	0 (0.0%)	5 (8.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	54 (88.5%)	6 (9.8%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	0 (0.0%)	68 (90.7%)	1 (1.3%)	0 (0.0%)	69 (92.0%)
		High	0 (0.0%)	4 (5.3%)	1 (1.3%)	0 (0.0%)	5 (6.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	73 (97.3%)	2 (2.7%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	61 (88.4%)	4 (5.8%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	0 (0.0%)	3 (4.3%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (89.9%)	7 (10.1%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (95.0%)	0 (0.0%)	0 (0.0%)	57 (95.0%)
		High	0 (0.0%)	0 (0.0%)	3 (5.0%)	0 (0.0%)	3 (5.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (95.0%)	3 (5.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	52 (89.7%)	2 (3.4%)	0 (0.0%)	54 (93.1%)
		High	0 (0.0%)	0 (0.0%)	4 (6.9%)	0 (0.0%)	4 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	52 (89.7%)	6 (10.3%)	0 (0.0%)	58 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	65 (92.9%)	1 (1.4%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (97.1%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	64 (88.9%)	4 (5.6%)	0 (0.0%)	68 (94.4%)
		High	0 (0.0%)	0 (0.0%)	3 (4.2%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (90.3%)	7 (9.7%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 20	Placebo	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	0 (0.0%)	53 (93.0%)	0 (0.0%)	0 (0.0%)	53 (93.0%)
		High	0 (0.0%)	0 (0.0%)	3 (5.3%)	0 (0.0%)	3 (5.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (94.7%)	3 (5.3%)	0 (0.0%)	57 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (86.2%)	2 (3.4%)	0 (0.0%)	52 (89.7%)
		High	0 (0.0%)	2 (3.4%)	4 (6.9%)	0 (0.0%)	6 (10.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	52 (89.7%)	6 (10.3%)	0 (0.0%)	58 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (92.5%)	1 (1.5%)	1 (1.5%)	64 (95.5%)
		High	0 (0.0%)	3 (4.5%)	0 (0.0%)	0 (0.0%)	3 (4.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (97.0%)	1 (1.5%)	1 (1.5%)	67 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	3 (4.2%)	0 (0.0%)	0 (0.0%)	3 (4.2%)
		Normal	0 (0.0%)	61 (84.7%)	3 (4.2%)	0 (0.0%)	64 (88.9%)
		High	0 (0.0%)	1 (1.4%)	4 (5.6%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (90.3%)	7 (9.7%)	0 (0.0%)	72 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (89.2%)	0 (0.0%)	0 (0.0%)	58 (89.2%)
		High	0 (0.0%)	4 (6.2%)	3 (4.6%)	0 (0.0%)	7 (10.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (95.4%)	3 (4.6%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (90.3%)	1 (1.6%)	0 (0.0%)	57 (91.9%)
		High	0 (0.0%)	0 (0.0%)	5 (8.1%)	0 (0.0%)	5 (8.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (90.3%)	6 (9.7%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (94.8%)	1 (1.3%)	1 (1.3%)	75 (97.4%)
		High	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	74 (96.1%)	2 (2.6%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	64 (87.7%)	2 (2.7%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	1 (1.4%)	5 (6.8%)	0 (0.0%)	6 (8.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	66 (90.4%)	7 (9.6%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (93.4%)	0 (0.0%)	0 (0.0%)	57 (93.4%)
		High	0 (0.0%)	1 (1.6%)	3 (4.9%)	0 (0.0%)	4 (6.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (95.1%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (90.9%)	1 (1.8%)	0 (0.0%)	51 (92.7%)
		High	0 (0.0%)	1 (1.8%)	3 (5.5%)	0 (0.0%)	4 (7.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	51 (92.7%)	4 (7.3%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (95.8%)	1 (1.4%)	1 (1.4%)	71 (98.6%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (95.8%)	2 (2.8%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	0 (0.0%)	52 (80.0%)	1 (1.5%)	0 (0.0%)	53 (81.5%)
		High	0 (0.0%)	5 (7.7%)	5 (7.7%)	0 (0.0%)	10 (15.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (90.8%)	6 (9.2%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	55 (88.7%)	0 (0.0%)	0 (0.0%)	55 (88.7%)
		High	0 (0.0%)	4 (6.5%)	3 (4.8%)	0 (0.0%)	7 (11.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (95.2%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	51 (92.7%)	1 (1.8%)	0 (0.0%)	52 (94.5%)
		High	0 (0.0%)	0 (0.0%)	3 (5.5%)	0 (0.0%)	3 (5.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	51 (92.7%)	4 (7.3%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	66 (94.3%)	1 (1.4%)	1 (1.4%)	68 (97.1%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (95.7%)	2 (2.9%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (82.4%)	2 (2.9%)	0 (0.0%)	58 (85.3%)
		High	0 (0.0%)	5 (7.4%)	5 (7.4%)	0 (0.0%)	10 (14.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (89.7%)	7 (10.3%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Platelet Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	9 (90.0%)	1 (10.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
		Normal	0 (0.0%)	4 (66.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
		High	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (16.7%)	4 (66.7%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline Low	Baseline Normal	Baseline High	Baseline Missing	Baseline Total
Week 4	Placebo	Low	0 (0.0%)	4 (5.6%)	0 (0.0%)	0 (0.0%)	4 (5.6%)
		Normal	1 (1.4%)	66 (91.7%)	0 (0.0%)	0 (0.0%)	67 (93.1%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	70 (97.2%)	1 (1.4%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	4 (6.1%)	0 (0.0%)	0 (0.0%)	5 (7.6%)
		Normal	1 (1.5%)	60 (90.9%)	0 (0.0%)	0 (0.0%)	61 (92.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.0%)	64 (97.0%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	2 (2.4%)	5 (6.0%)	0 (0.0%)	0 (0.0%)	7 (8.3%)
		Normal	2 (2.4%)	73 (86.9%)	1 (1.2%)	1 (1.2%)	77 (91.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (4.8%)	78 (92.9%)	1 (1.2%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	4 (5.3%)	4 (5.3%)	0 (0.0%)	0 (0.0%)	8 (10.5%)
		Normal	2 (2.6%)	66 (86.8%)	0 (0.0%)	0 (0.0%)	68 (89.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	6 (7.9%)	70 (92.1%)	0 (0.0%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	1 (1.5%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	63 (96.9%)	1 (1.5%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	2 (3.2%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	5 (8.1%)
		Normal	0 (0.0%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	57 (91.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	4 (5.2%)	0 (0.0%)	0 (0.0%)	5 (6.5%)
		Normal	3 (3.9%)	67 (87.0%)	1 (1.3%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.2%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	4 (5.5%)	3 (4.1%)	0 (0.0%)	0 (0.0%)	7 (9.6%)
		Normal	2 (2.7%)	64 (87.7%)	0 (0.0%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	6 (8.2%)	67 (91.8%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	3 (4.7%)	0 (0.0%)	0 (0.0%)	3 (4.7%)
		Normal	1 (1.6%)	59 (92.2%)	0 (0.0%)	0 (0.0%)	60 (93.8%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	62 (96.9%)	1 (1.6%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	3 (4.9%)
		Normal	1 (1.6%)	57 (93.4%)	0 (0.0%)	0 (0.0%)	58 (95.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	59 (96.7%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	3 (4.0%)	0 (0.0%)	0 (0.0%)	4 (5.3%)
		Normal	3 (4.0%)	67 (89.3%)	1 (1.3%)	0 (0.0%)	71 (94.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.3%)	70 (93.3%)	1 (1.3%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	3 (4.3%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	4 (5.8%)
		Normal	3 (4.3%)	62 (89.9%)	0 (0.0%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	6 (8.7%)	63 (91.3%)	0 (0.0%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	3 (4.9%)	0 (0.0%)	0 (0.0%)	3 (4.9%)
		Normal	1 (1.6%)	56 (91.8%)	0 (0.0%)	0 (0.0%)	57 (93.4%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	59 (96.7%)	1 (1.6%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	6 (10.2%)	0 (0.0%)	0 (0.0%)	6 (10.2%)
		Normal	0 (0.0%)	53 (89.8%)	0 (0.0%)	0 (0.0%)	53 (89.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	4 (5.7%)	0 (0.0%)	0 (0.0%)	5 (7.1%)
		Normal	3 (4.3%)	60 (85.7%)	1 (1.4%)	1 (1.4%)	65 (92.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.7%)	64 (91.4%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	5 (6.8%)	4 (5.5%)	0 (0.0%)	0 (0.0%)	9 (12.3%)
		Normal	1 (1.4%)	62 (84.9%)	0 (0.0%)	0 (0.0%)	63 (86.3%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	6 (8.2%)	67 (91.8%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	3 (5.1%)	0 (0.0%)	0 (0.0%)	3 (5.1%)
		Normal	1 (1.7%)	54 (91.5%)	0 (0.0%)	0 (0.0%)	55 (93.2%)
		High	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	57 (96.6%)	1 (1.7%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	0 (0.0%)	58 (96.7%)	0 (0.0%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (100.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	4 (5.8%)	63 (91.3%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.8%)	63 (91.3%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	3 (4.2%)	6 (8.3%)	0 (0.0%)	0 (0.0%)	9 (12.5%)
		Normal	3 (4.2%)	59 (81.9%)	0 (0.0%)	0 (0.0%)	62 (86.1%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	6 (8.3%)	66 (91.7%)	0 (0.0%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	1 (1.5%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	63 (96.9%)	1 (1.5%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	4 (6.3%)	0 (0.0%)	0 (0.0%)	5 (7.8%)
		Normal	0 (0.0%)	59 (92.2%)	0 (0.0%)	0 (0.0%)	59 (92.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	63 (98.4%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	4 (5.2%)	0 (0.0%)	0 (0.0%)	5 (6.5%)
		Normal	2 (2.6%)	68 (88.3%)	1 (1.3%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.9%)	72 (93.5%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	4 (5.5%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	6 (8.2%)
		Normal	3 (4.1%)	64 (87.7%)	0 (0.0%)	0 (0.0%)	67 (91.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	7 (9.6%)	66 (90.4%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Normal	1 (1.6%)	58 (93.5%)	0 (0.0%)	0 (0.0%)	59 (95.2%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (96.8%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	3 (5.4%)	0 (0.0%)	0 (0.0%)	4 (7.1%)
		Normal	0 (0.0%)	52 (92.9%)	0 (0.0%)	0 (0.0%)	52 (92.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.8%)	55 (98.2%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	4 (5.6%)	0 (0.0%)	0 (0.0%)	5 (6.9%)
		Normal	2 (2.8%)	63 (87.5%)	1 (1.4%)	1 (1.4%)	67 (93.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.2%)	67 (93.1%)	1 (1.4%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	5 (7.7%)	4 (6.2%)	0 (0.0%)	0 (0.0%)	9 (13.8%)
		Normal	2 (3.1%)	54 (83.1%)	0 (0.0%)	0 (0.0%)	56 (86.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	7 (10.8%)	58 (89.2%)	0 (0.0%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	58 (93.5%)	1 (1.6%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (96.8%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	0 (0.0%)	54 (98.2%)	0 (0.0%)	0 (0.0%)	54 (98.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.8%)	54 (98.2%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	2 (2.9%)	63 (90.0%)	1 (1.4%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	65 (92.9%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	3 (4.4%)	3 (4.4%)	0 (0.0%)	0 (0.0%)	6 (8.8%)
		Normal	4 (5.9%)	57 (83.8%)	0 (0.0%)	0 (0.0%)	61 (89.7%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	7 (10.3%)	61 (89.7%)	0 (0.0%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Red Blood Cell Count (x10^12/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	2 (16.7%)
		Normal	0 (0.0%)	10 (83.3%)	0 (0.0%)	0 (0.0%)	10 (83.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Normal	0 (0.0%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (12.5%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	61 (84.7%)	4 (5.6%)	0 (0.0%)	65 (90.3%)
		High	0 (0.0%)	2 (2.8%)	4 (5.6%)	0 (0.0%)	6 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (88.9%)	8 (11.1%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
		Normal	2 (3.0%)	59 (89.4%)	2 (3.0%)	0 (0.0%)	63 (95.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.5%)	61 (92.4%)	2 (3.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
		Normal	2 (2.4%)	73 (86.9%)	4 (4.8%)	1 (1.2%)	80 (95.2%)
		High	0 (0.0%)	1 (1.2%)	2 (2.4%)	0 (0.0%)	3 (3.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.4%)	75 (89.3%)	6 (7.1%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	3 (3.9%)	65 (85.5%)	3 (3.9%)	0 (0.0%)	71 (93.4%)
		High	0 (0.0%)	2 (2.6%)	2 (2.6%)	0 (0.0%)	4 (5.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.3%)	67 (88.2%)	5 (6.6%)	0 (0.0%)	76 (100.0%)

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Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	55 (84.6%)	4 (6.2%)	0 (0.0%)	59 (90.8%)
		High	0 (0.0%)	2 (3.1%)	4 (6.2%)	0 (0.0%)	6 (9.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (87.7%)	8 (12.3%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	3 (4.8%)	53 (85.5%)	2 (3.2%)	0 (0.0%)	58 (93.5%)
		High	0 (0.0%)	2 (3.2%)	1 (1.6%)	0 (0.0%)	3 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.8%)	56 (90.3%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	2 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	0 (0.0%)	64 (83.1%)	5 (6.5%)	1 (1.3%)	70 (90.9%)
		High	0 (0.0%)	5 (6.5%)	0 (0.0%)	0 (0.0%)	5 (6.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	69 (89.6%)	5 (6.5%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	3 (4.1%)	60 (82.2%)	3 (4.1%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	3 (4.1%)	2 (2.7%)	0 (0.0%)	5 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.5%)	64 (87.7%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (78.1%)	6 (9.4%)	0 (0.0%)	56 (87.5%)
		High	0 (0.0%)	6 (9.4%)	2 (3.1%)	0 (0.0%)	8 (12.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (87.5%)	8 (12.5%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	2 (3.3%)	53 (86.9%)	1 (1.6%)	0 (0.0%)	56 (91.8%)
		High	0 (0.0%)	1 (1.6%)	2 (3.3%)	0 (0.0%)	3 (4.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.9%)	55 (90.2%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	1 (1.3%)	64 (85.3%)	4 (5.3%)	0 (0.0%)	69 (92.0%)
		High	0 (0.0%)	3 (4.0%)	1 (1.3%)	0 (0.0%)	4 (5.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	68 (90.7%)	5 (6.7%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	3 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	1 (1.4%)	60 (87.0%)	4 (5.8%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.8%)	60 (87.0%)	5 (7.2%)	0 (0.0%)	69 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (82.0%)	4 (6.6%)	0 (0.0%)	54 (88.5%)
		High	0 (0.0%)	3 (4.9%)	4 (6.6%)	0 (0.0%)	7 (11.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	53 (86.9%)	8 (13.1%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	2 (3.4%)	51 (86.4%)	1 (1.7%)	0 (0.0%)	54 (91.5%)
		High	0 (0.0%)	2 (3.4%)	2 (3.4%)	0 (0.0%)	4 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.1%)	53 (89.8%)	3 (5.1%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	60 (85.7%)	5 (7.1%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	62 (88.6%)	5 (7.1%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	3 (4.1%)	61 (83.6%)	2 (2.7%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	2 (2.7%)	3 (4.1%)	0 (0.0%)	5 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.5%)	64 (87.7%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	48 (81.4%)	5 (8.5%)	0 (0.0%)	53 (89.8%)
		High	0 (0.0%)	4 (6.8%)	2 (3.4%)	0 (0.0%)	6 (10.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	52 (88.1%)	7 (11.9%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	2 (3.3%)	54 (90.0%)	1 (1.7%)	0 (0.0%)	57 (95.0%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.0%)	54 (90.0%)	3 (5.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.9%)	57 (82.6%)	3 (4.3%)	1 (1.4%)	63 (91.3%)
		High	0 (0.0%)	4 (5.8%)	2 (2.9%)	0 (0.0%)	6 (8.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	61 (88.4%)	5 (7.2%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Normal	3 (4.2%)	59 (81.9%)	3 (4.2%)	0 (0.0%)	65 (90.3%)
		High	0 (0.0%)	3 (4.2%)	2 (2.8%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.6%)	63 (87.5%)	5 (6.9%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	54 (83.1%)	3 (4.6%)	0 (0.0%)	57 (87.7%)
		High	0 (0.0%)	3 (4.6%)	5 (7.7%)	0 (0.0%)	8 (12.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (87.7%)	8 (12.3%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	2 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	1 (1.6%)	56 (87.5%)	1 (1.6%)	0 (0.0%)	58 (90.6%)
		High	0 (0.0%)	2 (3.1%)	2 (3.1%)	0 (0.0%)	4 (6.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	58 (90.6%)	3 (4.7%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	3 (3.9%)
		Normal	1 (1.3%)	66 (85.7%)	5 (6.5%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	68 (88.3%)	6 (7.8%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	4 (5.5%)	63 (86.3%)	3 (4.1%)	0 (0.0%)	70 (95.9%)
		High	0 (0.0%)	1 (1.4%)	2 (2.7%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.5%)	64 (87.7%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	51 (82.3%)	4 (6.5%)	0 (0.0%)	55 (88.7%)
		High	0 (0.0%)	3 (4.8%)	4 (6.5%)	0 (0.0%)	7 (11.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (87.1%)	8 (12.9%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (5.4%)	48 (85.7%)	2 (3.6%)	0 (0.0%)	53 (94.6%)
		High	0 (0.0%)	2 (3.6%)	1 (1.8%)	0 (0.0%)	3 (5.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.4%)	50 (89.3%)	3 (5.4%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	2 (2.8%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	3 (4.2%)
		Normal	0 (0.0%)	60 (83.3%)	2 (2.8%)	1 (1.4%)	63 (87.5%)
		High	0 (0.0%)	2 (2.8%)	4 (5.6%)	0 (0.0%)	6 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.8%)	63 (87.5%)	6 (8.3%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	2 (3.1%)	53 (81.5%)	0 (0.0%)	0 (0.0%)	55 (84.6%)
		High	0 (0.0%)	4 (6.2%)	4 (6.2%)	0 (0.0%)	8 (12.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.6%)	58 (89.2%)	4 (6.2%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	52 (83.9%)	5 (8.1%)	0 (0.0%)	57 (91.9%)
		High	0 (0.0%)	1 (1.6%)	3 (4.8%)	0 (0.0%)	4 (6.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (87.1%)	8 (12.9%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	1 (1.8%)	48 (87.3%)	1 (1.8%)	0 (0.0%)	50 (90.9%)
		High	0 (0.0%)	2 (3.6%)	2 (3.6%)	0 (0.0%)	4 (7.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	50 (90.9%)	3 (5.5%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	1 (1.4%)	61 (87.1%)	1 (1.4%)	1 (1.4%)	64 (91.4%)
		High	0 (0.0%)	1 (1.4%)	2 (2.9%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	64 (91.4%)	3 (4.3%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	2 (2.9%)	56 (82.4%)	2 (2.9%)	0 (0.0%)	60 (88.2%)
		High	0 (0.0%)	4 (5.9%)	3 (4.4%)	0 (0.0%)	7 (10.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.4%)	60 (88.2%)	5 (7.4%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: White Blood Cell Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	4 (66.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
		High	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	5 (83.3%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	11 (91.7%)
		High	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	1 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (83.3%)	2 (16.7%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	5 (62.5%)	1 (12.5%)	0 (0.0%)	6 (75.0%)
		High	0 (0.0%)	2 (25.0%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (98.6%)	0 (0.0%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	66 (100.0%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	66 (100.0%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	83 (98.8%)	0 (0.0%)	1 (1.2%)	84 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	83 (98.8%)	0 (0.0%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	76 (100.0%)	0 (0.0%)	0 (0.0%)	76 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	76 (100.0%)	0 (0.0%)	0 (0.0%)	76 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	65 (100.0%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (100.0%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (98.4%)	0 (0.0%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	75 (97.4%)	0 (0.0%)	1 (1.3%)	76 (98.7%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	76 (98.7%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (100.0%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (100.0%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (98.4%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (100.0%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	74 (98.7%)	0 (0.0%)	0 (0.0%)	74 (98.7%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (100.0%)	0 (0.0%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (100.0%)	0 (0.0%)	0 (0.0%)	69 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (100.0%)	0 (0.0%)	0 (0.0%)	69 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (98.4%)	0 (0.0%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (100.0%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (100.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (100.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (98.6%)	0 (0.0%)	1 (1.4%)	69 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (98.6%)	0 (0.0%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (98.6%)	0 (0.0%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (100.0%)	0 (0.0%)	0 (0.0%)	72 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (98.5%)	0 (0.0%)	0 (0.0%)	64 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (100.0%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (100.0%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (100.0%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	76 (98.7%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	76 (98.7%)	0 (0.0%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	73 (100.0%)	0 (0.0%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (100.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (100.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (98.6%)	0 (0.0%)	1 (1.4%)	72 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (98.6%)	0 (0.0%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (98.5%)	0 (0.0%)	0 (0.0%)	64 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (100.0%)	0 (0.0%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	55 (100.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (100.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (98.5%)	0 (0.0%)	0 (0.0%)	67 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (100.0%)	0 (0.0%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (95.8%)	2 (2.8%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (97.2%)	2 (2.8%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (95.5%)	2 (3.0%)	0 (0.0%)	65 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (97.0%)	2 (3.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	82 (97.6%)	0 (0.0%)	1 (1.2%)	83 (98.8%)
		High	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	83 (98.8%)	0 (0.0%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (96.1%)	2 (2.6%)	0 (0.0%)	75 (98.7%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	74 (97.4%)	2 (2.6%)	0 (0.0%)	76 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (98.5%)	1 (1.5%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (98.5%)	1 (1.5%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	2 (3.2%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	4 (5.2%)	0 (0.0%)	0 (0.0%)	4 (5.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (97.4%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (94.5%)	2 (2.7%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (97.3%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (95.3%)	2 (3.1%)	0 (0.0%)	63 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (96.9%)	2 (3.1%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (95.1%)	1 (1.6%)	0 (0.0%)	59 (96.7%)
		High	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (96.7%)	2 (3.3%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (94.7%)	0 (0.0%)	0 (0.0%)	71 (94.7%)
		High	0 (0.0%)	3 (4.0%)	1 (1.3%)	0 (0.0%)	4 (5.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	74 (98.7%)	1 (1.3%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (97.1%)	2 (2.9%)	0 (0.0%)	69 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (97.1%)	2 (2.9%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (96.7%)	1 (1.6%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (98.4%)	1 (1.6%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (94.9%)	2 (3.4%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (96.6%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (95.7%)	1 (1.4%)	1 (1.4%)	69 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (97.1%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (97.3%)	2 (2.7%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (97.3%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (96.6%)	1 (1.7%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (96.6%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (96.7%)	2 (3.3%)	0 (0.0%)	60 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (96.7%)	2 (3.3%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (91.3%)	1 (1.4%)	1 (1.4%)	65 (94.2%)
		High	0 (0.0%)	4 (5.8%)	0 (0.0%)	0 (0.0%)	4 (5.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (97.1%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (95.8%)	2 (2.8%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (97.2%)	2 (2.8%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (92.3%)	1 (1.5%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	3 (4.6%)	1 (1.5%)	0 (0.0%)	4 (6.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (95.3%)	2 (3.1%)	0 (0.0%)	63 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (96.9%)	2 (3.1%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	74 (96.1%)	1 (1.3%)	1 (1.3%)	76 (98.7%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (97.4%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	70 (95.9%)	2 (2.7%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (97.3%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	53 (94.6%)	2 (3.6%)	0 (0.0%)	55 (98.2%)
		High	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (96.4%)	2 (3.6%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	70 (97.2%)	1 (1.4%)	1 (1.4%)	72 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (97.2%)	1 (1.4%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (90.9%)	2 (3.6%)	0 (0.0%)	52 (94.5%)
		High	0 (0.0%)	3 (5.5%)	0 (0.0%)	0 (0.0%)	3 (5.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	53 (96.4%)	2 (3.6%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (97.1%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (97.1%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (98.5%)	1 (1.5%)	0 (0.0%)	68 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (98.5%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Basophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
		High	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	8 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (95.8%)	1 (1.4%)	0 (0.0%)	70 (97.2%)
		High	0 (0.0%)	0 (0.0%)	2 (2.8%)	0 (0.0%)	2 (2.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (95.8%)	3 (4.2%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (93.9%)	2 (3.0%)	0 (0.0%)	64 (97.0%)
		High	0 (0.0%)	0 (0.0%)	2 (3.0%)	0 (0.0%)	2 (3.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (93.9%)	4 (6.1%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	77 (91.7%)	4 (4.8%)	1 (1.2%)	82 (97.6%)
		High	0 (0.0%)	0 (0.0%)	2 (2.4%)	0 (0.0%)	2 (2.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	77 (91.7%)	6 (7.1%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	74 (97.4%)	0 (0.0%)	0 (0.0%)	74 (97.4%)
		High	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (98.7%)	1 (1.3%)	0 (0.0%)	76 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (93.8%)	1 (1.5%)	0 (0.0%)	62 (95.4%)
		High	0 (0.0%)	1 (1.5%)	2 (3.1%)	0 (0.0%)	3 (4.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (95.4%)	3 (4.6%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (93.5%)	4 (6.5%)	0 (0.0%)	62 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (93.5%)	4 (6.5%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	0 (0.0%)	4 (5.2%)	0 (0.0%)	4 (5.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (92.2%)	5 (6.5%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (93.8%)	2 (3.1%)	0 (0.0%)	62 (96.9%)
		High	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (95.3%)	3 (4.7%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (93.4%)	2 (3.3%)	0 (0.0%)	59 (96.7%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (93.4%)	4 (6.6%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (90.7%)	3 (4.0%)	0 (0.0%)	71 (94.7%)
		High	0 (0.0%)	1 (1.3%)	3 (4.0%)	0 (0.0%)	4 (5.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (92.0%)	6 (8.0%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (98.6%)	1 (1.4%)	0 (0.0%)	69 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (98.6%)	1 (1.4%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (95.1%)	2 (3.3%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (95.1%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	55 (93.2%)	3 (5.1%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (93.2%)	4 (6.8%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (90.0%)	4 (5.7%)	1 (1.4%)	68 (97.1%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (90.0%)	6 (8.6%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (94.9%)	2 (3.4%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (94.9%)	3 (5.1%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (93.3%)	2 (3.3%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (93.3%)	4 (6.7%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (88.4%)	4 (5.8%)	1 (1.4%)	66 (95.7%)
		High	0 (0.0%)	1 (1.4%)	2 (2.9%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (89.9%)	6 (8.7%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	70 (97.2%)	1 (1.4%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (98.6%)	1 (1.4%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (95.4%)	2 (3.1%)	0 (0.0%)	64 (98.5%)
		High	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (95.4%)	3 (4.6%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (92.2%)	3 (4.7%)	0 (0.0%)	62 (96.9%)
		High	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (93.8%)	4 (6.3%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (88.3%)	4 (5.2%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	1 (1.3%)	3 (3.9%)	0 (0.0%)	4 (5.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (89.6%)	7 (9.1%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (93.5%)	2 (3.2%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	51 (91.1%)	3 (5.4%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	1 (1.8%)	1 (1.8%)	0 (0.0%)	2 (3.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	52 (92.9%)	4 (7.1%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (87.5%)	4 (5.6%)	1 (1.4%)	68 (94.4%)
		High	0 (0.0%)	2 (2.8%)	2 (2.8%)	0 (0.0%)	4 (5.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (90.3%)	6 (8.3%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (98.5%)	1 (1.5%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (98.5%)	1 (1.5%)	0 (0.0%)	65 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	2 (3.2%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	51 (92.7%)	3 (5.5%)	0 (0.0%)	54 (98.2%)
		High	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	51 (92.7%)	4 (7.3%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (84.3%)	4 (5.7%)	1 (1.4%)	64 (91.4%)
		High	0 (0.0%)	3 (4.3%)	3 (4.3%)	0 (0.0%)	6 (8.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (88.6%)	7 (10.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (98.5%)	1 (1.5%)	0 (0.0%)	68 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (98.5%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	69 (95.8%)
		High	0 (0.0%)	1 (1.4%)	2 (2.8%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (97.2%)	2 (2.8%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (90.9%)	3 (4.5%)	0 (0.0%)	63 (95.5%)
		High	0 (0.0%)	1 (1.5%)	2 (3.0%)	0 (0.0%)	3 (4.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (92.4%)	5 (7.6%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	76 (90.5%)	1 (1.2%)	1 (1.2%)	78 (92.9%)
		High	0 (0.0%)	2 (2.4%)	4 (4.8%)	0 (0.0%)	6 (7.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	78 (92.9%)	5 (6.0%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	73 (96.1%)	0 (0.0%)	0 (0.0%)	73 (96.1%)
		High	0 (0.0%)	2 (2.6%)	1 (1.3%)	0 (0.0%)	3 (3.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (98.7%)	1 (1.3%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (95.4%)	1 (1.5%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	1 (1.5%)	1 (1.5%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (91.9%)	4 (6.5%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (91.9%)	5 (8.1%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	1 (1.3%)	3 (3.9%)	0 (0.0%)	4 (5.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (93.5%)	4 (5.2%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (93.8%)	1 (1.6%)	0 (0.0%)	61 (95.3%)
		High	0 (0.0%)	2 (3.1%)	1 (1.6%)	0 (0.0%)	3 (4.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (96.9%)	2 (3.1%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (91.8%)	3 (4.9%)	0 (0.0%)	59 (96.7%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (91.8%)	5 (8.2%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (92.0%)	1 (1.3%)	0 (0.0%)	70 (93.3%)
		High	0 (0.0%)	1 (1.3%)	4 (5.3%)	0 (0.0%)	5 (6.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (93.3%)	5 (6.7%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (97.1%)	0 (0.0%)	0 (0.0%)	67 (97.1%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	68 (98.6%)	1 (1.4%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	58 (95.1%)	2 (3.3%)	0 (0.0%)	60 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (96.7%)	2 (3.3%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	54 (91.5%)	2 (3.4%)	0 (0.0%)	56 (94.9%)
		High	0 (0.0%)	1 (1.7%)	2 (3.4%)	0 (0.0%)	3 (5.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (93.2%)	4 (6.8%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	64 (91.4%)	2 (2.9%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	0 (0.0%)	3 (4.3%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (91.4%)	5 (7.1%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (97.3%)	0 (0.0%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (94.9%)	2 (3.4%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (96.6%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (93.3%)	2 (3.3%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (93.3%)	4 (6.7%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (91.3%)	3 (4.3%)	1 (1.4%)	67 (97.1%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (91.3%)	5 (7.2%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	70 (97.2%)	1 (1.4%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	71 (98.6%)	1 (1.4%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	60 (92.3%)	1 (1.5%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	3 (4.6%)	1 (1.5%)	0 (0.0%)	4 (6.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (87.5%)	3 (4.7%)	0 (0.0%)	59 (92.2%)
		High	0 (0.0%)	3 (4.7%)	2 (3.1%)	0 (0.0%)	5 (7.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (92.2%)	5 (7.8%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (89.6%)	4 (5.2%)	1 (1.3%)	74 (96.1%)
		High	0 (0.0%)	1 (1.3%)	2 (2.6%)	0 (0.0%)	3 (3.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (90.9%)	6 (7.8%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	72 (98.6%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	1 (1.6%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (98.4%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	50 (89.3%)	4 (7.1%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	1 (1.8%)	1 (1.8%)	0 (0.0%)	2 (3.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	51 (91.1%)	5 (8.9%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	65 (90.3%)	3 (4.2%)	1 (1.4%)	69 (95.8%)
		High	0 (0.0%)	1 (1.4%)	2 (2.8%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	66 (91.7%)	5 (6.9%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (96.9%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	1 (1.5%)	1 (1.5%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (98.5%)	1 (1.5%)	0 (0.0%)	65 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	1 (1.6%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	2 (3.2%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (98.4%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	51 (92.7%)	3 (5.5%)	0 (0.0%)	54 (98.2%)
		High	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	51 (92.7%)	4 (7.3%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (84.3%)	4 (5.7%)	1 (1.4%)	64 (91.4%)
		High	0 (0.0%)	4 (5.7%)	2 (2.9%)	0 (0.0%)	6 (8.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (90.0%)	6 (8.6%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	67 (98.5%)	0 (0.0%)	0 (0.0%)	67 (98.5%)
		High	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	67 (98.5%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Eosinophils Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
		High	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	12 (100.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	67 (93.1%)	1 (1.4%)	0 (0.0%)	68 (94.4%)
		High	0 (0.0%)	0 (0.0%)	3 (4.2%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	67 (93.1%)	4 (5.6%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	0 (0.0%)	64 (97.0%)	0 (0.0%)	0 (0.0%)	64 (97.0%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	66 (100.0%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.2%)	79 (94.0%)	1 (1.2%)	1 (1.2%)	82 (97.6%)
		High	0 (0.0%)	2 (2.4%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.2%)	81 (96.4%)	1 (1.2%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.6%)	73 (96.1%)	1 (1.3%)	0 (0.0%)	76 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	73 (96.1%)	1 (1.3%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.5%)	59 (90.8%)	1 (1.5%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	2 (3.1%)	2 (3.1%)	0 (0.0%)	4 (6.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	61 (93.8%)	3 (4.6%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (100.0%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.3%)	72 (93.5%)	1 (1.3%)	1 (1.3%)	75 (97.4%)
		High	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	74 (96.1%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	59 (92.2%)	1 (1.6%)	0 (0.0%)	60 (93.8%)
		High	0 (0.0%)	1 (1.6%)	2 (3.1%)	0 (0.0%)	3 (4.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (93.8%)	3 (4.7%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	61 (100.0%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	61 (100.0%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.3%)	71 (94.7%)	1 (1.3%)	0 (0.0%)	73 (97.3%)
		High	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	73 (97.3%)	1 (1.3%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.9%)	65 (94.2%)	1 (1.4%)	0 (0.0%)	68 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	66 (95.7%)	1 (1.4%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.6%)	55 (90.2%)	1 (1.6%)	0 (0.0%)	57 (93.4%)
		High	0 (0.0%)	2 (3.3%)	2 (3.3%)	0 (0.0%)	4 (6.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	57 (93.4%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (96.6%)	0 (0.0%)	0 (0.0%)	57 (96.6%)
		High	0 (0.0%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	2 (3.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	59 (100.0%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.4%)	66 (94.3%)	1 (1.4%)	1 (1.4%)	69 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	67 (95.7%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.7%)	68 (93.2%)	1 (1.4%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.7%)	52 (88.1%)	2 (3.4%)	0 (0.0%)	55 (93.2%)
		High	0 (0.0%)	3 (5.1%)	1 (1.7%)	0 (0.0%)	4 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	55 (93.2%)	3 (5.1%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	57 (95.0%)	0 (0.0%)	0 (0.0%)	57 (95.0%)
		High	0 (0.0%)	3 (5.0%)	0 (0.0%)	0 (0.0%)	3 (5.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (100.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	62 (89.9%)	1 (1.4%)	1 (1.4%)	65 (94.2%)
		High	0 (0.0%)	3 (4.3%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	66 (95.7%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.8%)	67 (93.1%)	0 (0.0%)	0 (0.0%)	69 (95.8%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.8%)	69 (95.8%)	1 (1.4%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	62 (95.4%)	2 (3.1%)	0 (0.0%)	64 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	63 (96.9%)	2 (3.1%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	63 (98.4%)	0 (0.0%)	0 (0.0%)	63 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (100.0%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	0 (0.0%)	73 (94.8%)	1 (1.3%)	1 (1.3%)	75 (97.4%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	75 (97.4%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.7%)	70 (95.9%)	0 (0.0%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	2 (3.2%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	0 (0.0%)	55 (98.2%)	0 (0.0%)	0 (0.0%)	55 (98.2%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	56 (100.0%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	68 (94.4%)	0 (0.0%)	1 (1.4%)	69 (95.8%)
		High	0 (0.0%)	2 (2.8%)	1 (1.4%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (97.2%)	1 (1.4%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.1%)	61 (93.8%)	1 (1.5%)	0 (0.0%)	64 (98.5%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.1%)	62 (95.4%)	1 (1.5%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	59 (95.2%)	2 (3.2%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (96.8%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	2 (3.6%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
		Normal	0 (0.0%)	52 (94.5%)	0 (0.0%)	0 (0.0%)	52 (94.5%)
		High	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (100.0%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (98.6%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	2 (2.9%)	62 (91.2%)	1 (1.5%)	0 (0.0%)	65 (95.6%)
		High	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	65 (95.6%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline Low	Baseline Normal	Baseline High	Baseline Missing	Baseline Total
Early Term	Placebo	Low	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
		Normal	0 (0.0%)	8 (80.0%)	0 (0.0%)	0 (0.0%)	8 (80.0%)
		High	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (10.0%)	8 (80.0%)	1 (10.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (16.7%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (16.7%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (8.3%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (8.3%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 4	Placebo	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.8%)	68 (94.4%)	0 (0.0%)	0 (0.0%)	70 (97.2%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.2%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	2 (3.0%)	61 (92.4%)	1 (1.5%)	0 (0.0%)	64 (97.0%)
		High	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.0%)	62 (93.9%)	2 (3.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	1 (1.2%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Normal	1 (1.2%)	77 (91.7%)	2 (2.4%)	1 (1.2%)	81 (96.4%)
		High	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.4%)	79 (94.0%)	2 (2.4%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	2 (2.6%)	71 (93.4%)	1 (1.3%)	0 (0.0%)	74 (97.4%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	73 (96.1%)	1 (1.3%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 8	Placebo	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	2 (3.1%)	61 (93.8%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.6%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	2 (3.2%)	57 (91.9%)	2 (3.2%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	58 (93.5%)	2 (3.2%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	1 (1.3%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	74 (96.1%)
		High	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	73 (94.8%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.7%)	69 (94.5%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	1 (1.6%)	3 (4.7%)	0 (0.0%)	0 (0.0%)	4 (6.3%)
		Normal	2 (3.1%)	57 (89.1%)	0 (0.0%)	0 (0.0%)	59 (92.2%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.3%)	55 (90.2%)	2 (3.3%)	0 (0.0%)	59 (96.7%)
		High	0 (0.0%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	57 (93.4%)	2 (3.3%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.7%)	71 (94.7%)	0 (0.0%)	0 (0.0%)	73 (97.3%)
		High	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	72 (96.0%)	1 (1.3%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.9%)	63 (91.3%)	1 (1.4%)	0 (0.0%)	66 (95.7%)
		High	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	66 (95.7%)	1 (1.4%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 16	Placebo	Low	1 (1.6%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	3 (4.9%)
		Normal	2 (3.3%)	55 (90.2%)	0 (0.0%)	0 (0.0%)	57 (93.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.9%)	58 (95.1%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.4%)	55 (93.2%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.4%)	55 (93.2%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.4%)	66 (94.3%)	1 (1.4%)	1 (1.4%)	69 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	67 (95.7%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.7%)	69 (94.5%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 20	Placebo	Low	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	3 (5.1%)	53 (89.8%)	0 (0.0%)	0 (0.0%)	56 (94.9%)
		High	0 (0.0%)	2 (3.4%)	0 (0.0%)	0 (0.0%)	2 (3.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.1%)	56 (94.9%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.3%)	52 (86.7%)	2 (3.3%)	0 (0.0%)	56 (93.3%)
		High	0 (0.0%)	3 (5.0%)	1 (1.7%)	0 (0.0%)	4 (6.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	55 (91.7%)	3 (5.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.9%)	60 (87.0%)	1 (1.4%)	1 (1.4%)	64 (92.8%)
		High	0 (0.0%)	4 (5.8%)	0 (0.0%)	0 (0.0%)	4 (5.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	65 (94.2%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (2.8%)	67 (93.1%)	1 (1.4%)	0 (0.0%)	70 (97.2%)
		High	0 (0.0%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.8%)	69 (95.8%)	1 (1.4%)	0 (0.0%)	72 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 24	Placebo	Low	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	4 (6.2%)	59 (90.8%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.2%)	61 (93.8%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.1%)	58 (90.6%)	1 (1.6%)	0 (0.0%)	61 (95.3%)
		High	0 (0.0%)	1 (1.6%)	2 (3.1%)	0 (0.0%)	3 (4.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.1%)	59 (92.2%)	3 (4.7%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.3%)	72 (93.5%)	1 (1.3%)	1 (1.3%)	75 (97.4%)
		High	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	73 (94.8%)	2 (2.6%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.7%)	69 (94.5%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 32	Placebo	Low	1 (1.6%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	4 (6.5%)
		Normal	3 (4.8%)	52 (83.9%)	0 (0.0%)	0 (0.0%)	55 (88.7%)
		High	0 (0.0%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.5%)	58 (93.5%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	2 (3.6%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
		Normal	2 (3.6%)	49 (87.5%)	3 (5.4%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	51 (91.1%)	3 (5.4%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	3 (4.2%)
		Normal	0 (0.0%)	64 (88.9%)	2 (2.8%)	1 (1.4%)	67 (93.1%)
		High	0 (0.0%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	68 (94.4%)	2 (2.8%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	3 (4.6%)	0 (0.0%)	0 (0.0%)	3 (4.6%)
		Normal	2 (3.1%)	60 (92.3%)	0 (0.0%)	0 (0.0%)	62 (95.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.1%)	63 (96.9%)	0 (0.0%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 40	Placebo	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	3 (4.8%)	57 (91.9%)	0 (0.0%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.5%)	58 (93.5%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	4 (7.3%)	0 (0.0%)	0 (0.0%)	4 (7.3%)
		Normal	2 (3.6%)	47 (85.5%)	1 (1.8%)	0 (0.0%)	50 (90.9%)
		High	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	51 (92.7%)	2 (3.6%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	62 (88.6%)	2 (2.9%)	1 (1.4%)	66 (94.3%)
		High	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	66 (94.3%)	2 (2.9%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	4 (5.9%)	0 (0.0%)	0 (0.0%)	4 (5.9%)
		Normal	2 (2.9%)	61 (89.7%)	1 (1.5%)	0 (0.0%)	64 (94.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	65 (95.6%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Lymphocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Early Term	Placebo	Low	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
		Normal	0 (0.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (10.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
		Normal	0 (0.0%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (16.7%)	5 (83.3%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (8.3%)	11 (91.7%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (8.3%)	11 (91.7%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Normal	2 (25.0%)	5 (62.5%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (25.0%)	6 (75.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (4.2%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	72 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.2%)	69 (95.8%)	0 (0.0%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	2 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
		Normal	1 (1.5%)	63 (95.5%)	0 (0.0%)	0 (0.0%)	64 (97.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.5%)	63 (95.5%)	0 (0.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	2 (2.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Normal	1 (1.2%)	79 (94.0%)	1 (1.2%)	1 (1.2%)	82 (97.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.6%)	79 (94.0%)	1 (1.2%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	0 (0.0%)	74 (97.4%)	1 (1.3%)	0 (0.0%)	75 (98.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	74 (97.4%)	1 (1.3%)	0 (0.0%)	76 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (4.6%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.6%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Normal	2 (3.2%)	58 (93.5%)	0 (0.0%)	0 (0.0%)	60 (96.8%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.8%)	59 (95.2%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	1 (1.3%)	71 (92.2%)	1 (1.3%)	1 (1.3%)	74 (96.1%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	73 (94.8%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	2 (3.1%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	63 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	2 (3.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	3 (4.9%)
		Normal	1 (1.6%)	57 (93.4%)	0 (0.0%)	0 (0.0%)	58 (95.1%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.9%)	58 (95.1%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	4 (5.3%)	0 (0.0%)	0 (0.0%)	5 (6.7%)
		Normal	1 (1.3%)	68 (90.7%)	0 (0.0%)	0 (0.0%)	69 (92.0%)
		High	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.7%)	72 (96.0%)	1 (1.3%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	67 (97.1%)	0 (0.0%)	0 (0.0%)	67 (97.1%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	67 (97.1%)	1 (1.4%)	0 (0.0%)	69 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (4.9%)	58 (95.1%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.9%)	58 (95.1%)	0 (0.0%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	3 (5.1%)	55 (93.2%)	0 (0.0%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.1%)	56 (94.9%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	65 (92.9%)	1 (1.4%)	1 (1.4%)	68 (97.1%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	66 (94.3%)	1 (1.4%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	0 (0.0%)	70 (95.9%)	1 (1.4%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	1 (1.7%)	56 (94.9%)	0 (0.0%)	0 (0.0%)	57 (96.6%)
		High	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.4%)	57 (96.6%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	2 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	1 (1.7%)	57 (95.0%)	0 (0.0%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.0%)	57 (95.0%)	0 (0.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	65 (94.2%)	1 (1.4%)	1 (1.4%)	68 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	65 (94.2%)	1 (1.4%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	70 (97.2%)	1 (1.4%)	0 (0.0%)	71 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	70 (97.2%)	1 (1.4%)	0 (0.0%)	72 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	2 (3.1%)	61 (93.8%)	0 (0.0%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.6%)	62 (95.4%)	0 (0.0%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	2 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	1 (1.6%)	60 (93.8%)	0 (0.0%)	0 (0.0%)	61 (95.3%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	61 (95.3%)	0 (0.0%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	2 (2.6%)	3 (3.9%)	0 (0.0%)	0 (0.0%)	5 (6.5%)
		Normal	0 (0.0%)	70 (90.9%)	1 (1.3%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	73 (94.8%)	1 (1.3%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	71 (97.3%)	1 (1.4%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	2 (3.2%)	59 (95.2%)	0 (0.0%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	2 (3.6%)	52 (92.9%)	0 (0.0%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.4%)	53 (94.6%)	0 (0.0%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	2 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Normal	0 (0.0%)	66 (91.7%)	0 (0.0%)	1 (1.4%)	67 (93.1%)
		High	0 (0.0%)	2 (2.8%)	1 (1.4%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.8%)	68 (94.4%)	1 (1.4%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	0 (0.0%)	60 (92.3%)	1 (1.5%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	3 (4.6%)	0 (0.0%)	0 (0.0%)	3 (4.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	63 (96.9%)	1 (1.5%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.2%)	59 (95.2%)	0 (0.0%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	60 (96.8%)	0 (0.0%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	2 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
		Normal	1 (1.8%)	49 (89.1%)	0 (0.0%)	0 (0.0%)	50 (90.9%)
		High	0 (0.0%)	3 (5.5%)	0 (0.0%)	0 (0.0%)	3 (5.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.5%)	52 (94.5%)	0 (0.0%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	67 (95.7%)	0 (0.0%)	1 (1.4%)	69 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.9%)	67 (95.7%)	0 (0.0%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	0 (0.0%)	65 (95.6%)	0 (0.0%)	0 (0.0%)	65 (95.6%)
		High	0 (0.0%)	1 (1.5%)	1 (1.5%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	66 (97.1%)	1 (1.5%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	6 (100.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (8.3%)	10 (83.3%)	0 (0.0%)	0 (0.0%)	11 (91.7%)
		High	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	1 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (8.3%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	3 (4.2%)	0 (0.0%)	0 (0.0%)	3 (4.2%)
		Normal	4 (5.6%)	58 (80.6%)	1 (1.4%)	0 (0.0%)	63 (87.5%)
		High	0 (0.0%)	3 (4.2%)	3 (4.2%)	0 (0.0%)	6 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (5.6%)	64 (88.9%)	4 (5.6%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.5%)	61 (92.4%)	1 (1.5%)	0 (0.0%)	63 (95.5%)
		High	0 (0.0%)	3 (4.5%)	0 (0.0%)	0 (0.0%)	3 (4.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	64 (97.0%)	1 (1.5%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	1 (1.2%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	2 (2.4%)
		Normal	2 (2.4%)	74 (88.1%)	4 (4.8%)	1 (1.2%)	81 (96.4%)
		High	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)	1 (1.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.6%)	75 (89.3%)	5 (6.0%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	3 (3.9%)	0 (0.0%)	0 (0.0%)	3 (3.9%)
		Normal	3 (3.9%)	67 (88.2%)	2 (2.6%)	0 (0.0%)	72 (94.7%)
		High	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.9%)	71 (93.4%)	2 (2.6%)	0 (0.0%)	76 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 8	Placebo	Low	3 (4.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (4.6%)
		Normal	1 (1.5%)	55 (84.6%)	1 (1.5%)	0 (0.0%)	57 (87.7%)
		High	0 (0.0%)	2 (3.1%)	3 (4.6%)	0 (0.0%)	5 (7.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.2%)	57 (87.7%)	4 (6.2%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	56 (90.3%)	1 (1.6%)	0 (0.0%)	58 (93.5%)
		High	0 (0.0%)	3 (4.8%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (96.8%)	1 (1.6%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	3 (3.9%)	66 (85.7%)	3 (3.9%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	0 (0.0%)	2 (2.6%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (3.9%)	68 (88.3%)	5 (6.5%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	3 (4.1%)	67 (91.8%)	2 (2.7%)	0 (0.0%)	72 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.1%)	68 (93.2%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 12	Placebo	Low	2 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	2 (3.1%)	52 (81.3%)	3 (4.7%)	0 (0.0%)	57 (89.1%)
		High	0 (0.0%)	4 (6.3%)	1 (1.6%)	0 (0.0%)	5 (7.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.3%)	56 (87.5%)	4 (6.3%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.6%)	59 (96.7%)	1 (1.6%)	0 (0.0%)	61 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	59 (96.7%)	1 (1.6%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	3 (4.0%)
		Normal	2 (2.7%)	64 (85.3%)	3 (4.0%)	0 (0.0%)	69 (92.0%)
		High	0 (0.0%)	1 (1.3%)	2 (2.7%)	0 (0.0%)	3 (4.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.0%)	67 (89.3%)	5 (6.7%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	3 (4.3%)	62 (89.9%)	1 (1.4%)	0 (0.0%)	66 (95.7%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	64 (92.8%)	2 (2.9%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 16	Placebo	Low	0 (0.0%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	4 (6.6%)	51 (83.6%)	1 (1.6%)	0 (0.0%)	56 (91.8%)
		High	0 (0.0%)	1 (1.6%)	2 (3.3%)	0 (0.0%)	3 (4.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.6%)	54 (88.5%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	1 (1.7%)	57 (96.6%)	0 (0.0%)	0 (0.0%)	58 (98.3%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	58 (98.3%)	0 (0.0%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	3 (4.3%)	59 (84.3%)	3 (4.3%)	1 (1.4%)	66 (94.3%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	61 (87.1%)	5 (7.1%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	3 (4.1%)	62 (84.9%)	2 (2.7%)	0 (0.0%)	67 (91.8%)
		High	0 (0.0%)	4 (5.5%)	0 (0.0%)	0 (0.0%)	4 (5.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.1%)	68 (93.2%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 20	Placebo	Low	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	2 (3.4%)
		Normal	2 (3.4%)	50 (84.7%)	1 (1.7%)	0 (0.0%)	53 (89.8%)
		High	0 (0.0%)	3 (5.1%)	1 (1.7%)	0 (0.0%)	4 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.1%)	54 (91.5%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.7%)	56 (93.3%)	1 (1.7%)	0 (0.0%)	58 (96.7%)
		High	0 (0.0%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	58 (96.7%)	1 (1.7%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	3 (4.3%)	58 (84.1%)	4 (5.8%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	1 (1.4%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.3%)	59 (85.5%)	6 (8.7%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (4.2%)	62 (86.1%)	2 (2.8%)	0 (0.0%)	67 (93.1%)
		High	0 (0.0%)	5 (6.9%)	0 (0.0%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.2%)	67 (93.1%)	2 (2.8%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 24	Placebo	Low	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	5 (7.7%)	54 (83.1%)	3 (4.6%)	0 (0.0%)	62 (95.4%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.7%)	57 (87.7%)	3 (4.6%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	59 (92.2%)	1 (1.6%)	0 (0.0%)	61 (95.3%)
		High	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	62 (96.9%)	1 (1.6%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.6%)
		Normal	2 (2.6%)	66 (85.7%)	4 (5.2%)	1 (1.3%)	73 (94.8%)
		High	0 (0.0%)	1 (1.3%)	1 (1.3%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.6%)	68 (88.3%)	6 (7.8%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (4.1%)	65 (89.0%)	2 (2.7%)	0 (0.0%)	70 (95.9%)
		High	0 (0.0%)	3 (4.1%)	0 (0.0%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.1%)	68 (93.2%)	2 (2.7%)	0 (0.0%)	73 (100.0%)

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Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	2 (3.2%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	3 (4.8%)
		Normal	3 (4.8%)	52 (83.9%)	3 (4.8%)	0 (0.0%)	58 (93.5%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	54 (87.1%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	1 (1.8%)	52 (92.9%)	1 (1.8%)	0 (0.0%)	54 (96.4%)
		High	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.8%)	54 (96.4%)	1 (1.8%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	2 (2.8%)	60 (83.3%)	3 (4.2%)	1 (1.4%)	66 (91.7%)
		High	0 (0.0%)	3 (4.2%)	2 (2.8%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (2.8%)	64 (88.9%)	5 (6.9%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	2 (3.1%)	57 (87.7%)	2 (3.1%)	0 (0.0%)	61 (93.8%)
		High	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.6%)	60 (92.3%)	2 (3.1%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	5 (8.1%)	53 (85.5%)	3 (4.8%)	0 (0.0%)	61 (98.4%)
		High	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (8.1%)	54 (87.1%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	1 (1.8%)	48 (87.3%)	1 (1.8%)	0 (0.0%)	50 (90.9%)
		High	0 (0.0%)	4 (7.3%)	0 (0.0%)	0 (0.0%)	4 (7.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.8%)	53 (96.4%)	1 (1.8%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	3 (4.3%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	1 (1.4%)	59 (84.3%)	4 (5.7%)	1 (1.4%)	65 (92.9%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	62 (88.6%)	6 (8.6%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	3 (4.4%)	60 (88.2%)	2 (2.9%)	0 (0.0%)	65 (95.6%)
		High	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.4%)	63 (92.6%)	2 (2.9%)	0 (0.0%)	68 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Monocytes Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
		Normal	0 (0.0%)	8 (80.0%)	1 (10.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	9 (90.0%)	1 (10.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
		Normal	0 (0.0%)	3 (50.0%)	1 (16.7%)	0 (0.0%)	4 (66.7%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	5 (83.3%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (25.0%)	8 (66.7%)	0 (0.0%)	0 (0.0%)	11 (91.7%)
		High	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	1 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (25.0%)	9 (75.0%)	0 (0.0%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	7 (87.5%)	0 (0.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (100.0%)	0 (0.0%)	0 (0.0%)	8 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Banded Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Normal	High	Missing	Total
Week 4	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	64 (88.9%)	3 (4.2%)	0 (0.0%)	67 (93.1%)
		High	0 (0.0%)	0 (0.0%)	4 (5.6%)	0 (0.0%)	4 (5.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	65 (90.3%)	7 (9.7%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	1 (1.5%)	60 (90.9%)	2 (3.0%)	0 (0.0%)	63 (95.5%)
		High	0 (0.0%)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.0%)	62 (93.9%)	2 (3.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
		Normal	1 (1.2%)	72 (85.7%)	5 (6.0%)	1 (1.2%)	79 (94.0%)
		High	0 (0.0%)	3 (3.6%)	1 (1.2%)	0 (0.0%)	4 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.2%)	76 (90.5%)	6 (7.1%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.3%)	67 (88.2%)	6 (7.9%)	0 (0.0%)	74 (97.4%)
		High	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	69 (90.8%)	6 (7.9%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	54 (83.1%)	4 (6.2%)	0 (0.0%)	58 (89.2%)
		High	0 (0.0%)	4 (6.2%)	3 (4.6%)	0 (0.0%)	7 (10.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (89.2%)	7 (10.8%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.2%)	52 (83.9%)	3 (4.8%)	0 (0.0%)	57 (91.9%)
		High	0 (0.0%)	5 (8.1%)	0 (0.0%)	0 (0.0%)	5 (8.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.2%)	57 (91.9%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	0 (0.0%)	66 (85.7%)	3 (3.9%)	1 (1.3%)	70 (90.9%)
		High	0 (0.0%)	2 (2.6%)	3 (3.9%)	0 (0.0%)	5 (6.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	70 (90.9%)	6 (7.8%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.4%)	65 (89.0%)	4 (5.5%)	0 (0.0%)	70 (95.9%)
		High	0 (0.0%)	1 (1.4%)	2 (2.7%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	66 (90.4%)	6 (8.2%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	53 (82.8%)	3 (4.7%)	0 (0.0%)	56 (87.5%)
		High	0 (0.0%)	4 (6.3%)	4 (6.3%)	0 (0.0%)	8 (12.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	57 (89.1%)	7 (10.9%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	2 (3.3%)	56 (91.8%)	1 (1.6%)	0 (0.0%)	59 (96.7%)
		High	0 (0.0%)	0 (0.0%)	1 (1.6%)	0 (0.0%)	1 (1.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.3%)	57 (93.4%)	2 (3.3%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	0 (0.0%)	68 (90.7%)	5 (6.7%)	0 (0.0%)	73 (97.3%)
		High	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	1 (1.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	69 (92.0%)	6 (8.0%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	59 (85.5%)	5 (7.2%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	2 (2.9%)	1 (1.4%)	0 (0.0%)	3 (4.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	62 (89.9%)	6 (8.7%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	52 (85.2%)	4 (6.6%)	0 (0.0%)	56 (91.8%)
		High	0 (0.0%)	2 (3.3%)	3 (4.9%)	0 (0.0%)	5 (8.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (88.5%)	7 (11.5%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.4%)	54 (91.5%)	1 (1.7%)	0 (0.0%)	57 (96.6%)
		High	0 (0.0%)	1 (1.7%)	1 (1.7%)	0 (0.0%)	2 (3.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.4%)	55 (93.2%)	2 (3.4%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	0 (0.0%)	63 (90.0%)	5 (7.1%)	1 (1.4%)	69 (98.6%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	64 (91.4%)	5 (7.1%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	64 (87.7%)	4 (5.5%)	0 (0.0%)	69 (94.5%)
		High	0 (0.0%)	1 (1.4%)	2 (2.7%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	66 (90.4%)	6 (8.2%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	54 (91.5%)	3 (5.1%)	0 (0.0%)	57 (96.6%)
		High	0 (0.0%)	0 (0.0%)	2 (3.4%)	0 (0.0%)	2 (3.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	54 (91.5%)	5 (8.5%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	1 (1.7%)	2 (3.3%)	0 (0.0%)	0 (0.0%)	3 (5.0%)
		Normal	2 (3.3%)	50 (83.3%)	1 (1.7%)	0 (0.0%)	53 (88.3%)
		High	0 (0.0%)	3 (5.0%)	1 (1.7%)	0 (0.0%)	4 (6.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.0%)	55 (91.7%)	2 (3.3%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	4 (5.8%)	0 (0.0%)	0 (0.0%)	4 (5.8%)
		Normal	0 (0.0%)	53 (76.8%)	6 (8.7%)	1 (1.4%)	60 (87.0%)
		High	0 (0.0%)	5 (7.2%)	0 (0.0%)	0 (0.0%)	5 (7.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	62 (89.9%)	6 (8.7%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	62 (86.1%)	5 (6.9%)	0 (0.0%)	68 (94.4%)
		High	0 (0.0%)	2 (2.8%)	1 (1.4%)	0 (0.0%)	3 (4.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	65 (90.3%)	6 (8.3%)	0 (0.0%)	72 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	56 (86.2%)	7 (10.8%)	0 (0.0%)	63 (96.9%)
		High	0 (0.0%)	2 (3.1%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	58 (89.2%)	7 (10.8%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	2 (3.1%)	56 (87.5%)	1 (1.6%)	0 (0.0%)	59 (92.2%)
		High	0 (0.0%)	3 (4.7%)	1 (1.6%)	0 (0.0%)	4 (6.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.7%)	59 (92.2%)	2 (3.1%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	1 (1.3%)	63 (81.8%)	3 (3.9%)	1 (1.3%)	68 (88.3%)
		High	0 (0.0%)	6 (7.8%)	1 (1.3%)	0 (0.0%)	7 (9.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	71 (92.2%)	4 (5.2%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.4%)	66 (90.4%)	4 (5.5%)	0 (0.0%)	71 (97.3%)
		High	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	67 (91.8%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 32	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	53 (85.5%)	5 (8.1%)	0 (0.0%)	58 (93.5%)
		High	0 (0.0%)	1 (1.6%)	2 (3.2%)	0 (0.0%)	3 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (88.7%)	7 (11.3%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	3 (5.4%)	48 (85.7%)	1 (1.8%)	0 (0.0%)	52 (92.9%)
		High	0 (0.0%)	3 (5.4%)	1 (1.8%)	0 (0.0%)	4 (7.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (5.4%)	51 (91.1%)	2 (3.6%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.8%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Normal	1 (1.4%)	62 (86.1%)	2 (2.8%)	1 (1.4%)	66 (91.7%)
		High	0 (0.0%)	2 (2.8%)	2 (2.8%)	0 (0.0%)	4 (5.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	66 (91.7%)	4 (5.6%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	0 (0.0%)	57 (87.7%)	2 (3.1%)	0 (0.0%)	59 (90.8%)
		High	0 (0.0%)	2 (3.1%)	3 (4.6%)	0 (0.0%)	5 (7.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	60 (92.3%)	5 (7.7%)	0 (0.0%)	65 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group	Baseline	Low	Normal	High	Missing	Total
Week 40	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	54 (87.1%)	5 (8.1%)	0 (0.0%)	59 (95.2%)
		High	0 (0.0%)	1 (1.6%)	2 (3.2%)	0 (0.0%)	3 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	55 (88.7%)	7 (11.3%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	2 (3.6%)	47 (85.5%)	1 (1.8%)	0 (0.0%)	50 (90.9%)
		High	0 (0.0%)	4 (7.3%)	1 (1.8%)	0 (0.0%)	5 (9.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	2 (3.6%)	51 (92.7%)	2 (3.6%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	60 (85.7%)	2 (2.9%)	1 (1.4%)	64 (91.4%)
		High	0 (0.0%)	3 (4.3%)	1 (1.4%)	0 (0.0%)	4 (5.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	65 (92.9%)	3 (4.3%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (1.5%)
		Normal	1 (1.5%)	58 (85.3%)	3 (4.4%)	0 (0.0%)	62 (91.2%)
		High	0 (0.0%)	3 (4.4%)	2 (2.9%)	0 (0.0%)	5 (7.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	62 (91.2%)	5 (7.4%)	0 (0.0%)	68 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Segmented Percent (FRACTION)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	8 (80.0%)	1 (10.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	8 (80.0%)	2 (20.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	3 (50.0%)	1 (16.7%)	0 (0.0%)	4 (66.7%)
		High	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	4 (66.7%)	2 (33.3%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	11 (91.7%)
		High	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	1 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (83.3%)	2 (16.7%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	5 (62.5%)	2 (25.0%)	0 (0.0%)	7 (87.5%)
		High	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (12.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	5 (62.5%)	3 (37.5%)	0 (0.0%)	8 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Bands Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline Low	Baseline Normal	Baseline High	Baseline Missing	Baseline Total
Week 4	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Bands Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline Low	Baseline Normal	Baseline High	Baseline Missing	Baseline Total
Week 20	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
		High	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 4	Placebo	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	1 (1.4%)	58 (80.6%)	4 (5.6%)	0 (0.0%)	63 (87.5%)
		High	0 (0.0%)	4 (5.6%)	4 (5.6%)	0 (0.0%)	8 (11.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	63 (87.5%)	8 (11.1%)	0 (0.0%)	72 (100.0%)
	Omalizumab 75mg	Low	1 (1.5%)	2 (3.0%)	0 (0.0%)	0 (0.0%)	3 (4.5%)
		Normal	0 (0.0%)	59 (89.4%)	2 (3.0%)	0 (0.0%)	61 (92.4%)
		High	0 (0.0%)	2 (3.0%)	0 (0.0%)	0 (0.0%)	2 (3.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	63 (95.5%)	2 (3.0%)	0 (0.0%)	66 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (1.2%)
		Normal	1 (1.2%)	73 (86.9%)	4 (4.8%)	1 (1.2%)	79 (94.0%)
		High	0 (0.0%)	2 (2.4%)	2 (2.4%)	0 (0.0%)	4 (4.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.2%)	76 (90.5%)	6 (7.1%)	1 (1.2%)	84 (100.0%)
	Omalizumab 300mg	Low	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.3%)
		Normal	4 (5.3%)	64 (84.2%)	2 (2.6%)	0 (0.0%)	70 (92.1%)
		High	0 (0.0%)	2 (2.6%)	3 (3.9%)	0 (0.0%)	5 (6.6%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.6%)	66 (86.8%)	5 (6.6%)	0 (0.0%)	76 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 8	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.5%)	51 (78.5%)	4 (6.2%)	0 (0.0%)	56 (86.2%)
		High	0 (0.0%)	5 (7.7%)	4 (6.2%)	0 (0.0%)	9 (13.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	56 (86.2%)	8 (12.3%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.6%)	53 (85.5%)	2 (3.2%)	0 (0.0%)	56 (90.3%)
		High	0 (0.0%)	5 (8.1%)	1 (1.6%)	0 (0.0%)	6 (9.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	58 (93.5%)	3 (4.8%)	0 (0.0%)	62 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	0 (0.0%)	63 (81.8%)	5 (6.5%)	1 (1.3%)	69 (89.6%)
		High	0 (0.0%)	6 (7.8%)	0 (0.0%)	0 (0.0%)	6 (7.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	70 (90.9%)	5 (6.5%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
		Normal	5 (6.8%)	58 (79.5%)	3 (4.1%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	3 (4.1%)	2 (2.7%)	0 (0.0%)	5 (6.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	63 (86.3%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 12	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.6%)	51 (79.7%)	5 (7.8%)	0 (0.0%)	57 (89.1%)
		High	0 (0.0%)	4 (6.3%)	3 (4.7%)	0 (0.0%)	7 (10.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	55 (85.9%)	8 (12.5%)	0 (0.0%)	64 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	0 (0.0%)	55 (90.2%)	2 (3.3%)	0 (0.0%)	57 (93.4%)
		High	0 (0.0%)	1 (1.6%)	1 (1.6%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	57 (93.4%)	3 (4.9%)	0 (0.0%)	61 (100.0%)
	Omalizumab 150mg	Low	1 (1.3%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	3 (4.0%)
		Normal	0 (0.0%)	65 (86.7%)	4 (5.3%)	0 (0.0%)	69 (92.0%)
		High	0 (0.0%)	2 (2.7%)	1 (1.3%)	0 (0.0%)	3 (4.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	69 (92.0%)	5 (6.7%)	0 (0.0%)	75 (100.0%)
	Omalizumab 300mg	Low	2 (2.9%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	3 (4.3%)
		Normal	3 (4.3%)	57 (82.6%)	5 (7.2%)	0 (0.0%)	65 (94.2%)
		High	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (7.2%)	59 (85.5%)	5 (7.2%)	0 (0.0%)	69 (100.0%)

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 16	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	49 (80.3%)	4 (6.6%)	0 (0.0%)	54 (88.5%)
		High	0 (0.0%)	2 (3.3%)	4 (6.6%)	0 (0.0%)	6 (9.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	52 (85.2%)	8 (13.1%)	0 (0.0%)	61 (100.0%)
	Omalizumab 75mg	Low	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)
		Normal	0 (0.0%)	53 (89.8%)	2 (3.4%)	0 (0.0%)	55 (93.2%)
		High	0 (0.0%)	2 (3.4%)	1 (1.7%)	0 (0.0%)	3 (5.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	55 (93.2%)	3 (5.1%)	0 (0.0%)	59 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	0 (0.0%)	62 (88.6%)	4 (5.7%)	1 (1.4%)	67 (95.7%)
		High	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	63 (90.0%)	5 (7.1%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
		Normal	5 (6.8%)	59 (80.8%)	2 (2.7%)	0 (0.0%)	66 (90.4%)
		High	0 (0.0%)	3 (4.1%)	3 (4.1%)	0 (0.0%)	6 (8.2%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	63 (86.3%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 20	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.7%)	49 (83.1%)	4 (6.8%)	0 (0.0%)	54 (91.5%)
		High	0 (0.0%)	3 (5.1%)	2 (3.4%)	0 (0.0%)	5 (8.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	52 (88.1%)	6 (10.2%)	0 (0.0%)	59 (100.0%)
	Omalizumab 75mg	Low	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	2 (3.3%)
		Normal	0 (0.0%)	55 (91.7%)	1 (1.7%)	0 (0.0%)	56 (93.3%)
		High	0 (0.0%)	0 (0.0%)	2 (3.3%)	0 (0.0%)	2 (3.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.7%)	56 (93.3%)	3 (5.0%)	0 (0.0%)	60 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	2 (2.9%)
		Normal	1 (1.4%)	56 (81.2%)	2 (2.9%)	1 (1.4%)	60 (87.0%)
		High	0 (0.0%)	5 (7.2%)	2 (2.9%)	0 (0.0%)	7 (10.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	62 (89.9%)	5 (7.2%)	1 (1.4%)	69 (100.0%)
	Omalizumab 300mg	Low	3 (4.2%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	4 (5.6%)
		Normal	2 (2.8%)	58 (80.6%)	3 (4.2%)	0 (0.0%)	63 (87.5%)
		High	0 (0.0%)	3 (4.2%)	2 (2.8%)	0 (0.0%)	5 (6.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.9%)	62 (86.1%)	5 (6.9%)	0 (0.0%)	72 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 24	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.5%)	53 (81.5%)	4 (6.2%)	0 (0.0%)	58 (89.2%)
		High	0 (0.0%)	3 (4.6%)	4 (6.2%)	0 (0.0%)	7 (10.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.5%)	56 (86.2%)	8 (12.3%)	0 (0.0%)	65 (100.0%)
	Omalizumab 75mg	Low	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	0 (0.0%)	57 (89.1%)	1 (1.6%)	0 (0.0%)	58 (90.6%)
		High	0 (0.0%)	3 (4.7%)	2 (3.1%)	0 (0.0%)	5 (7.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	60 (93.8%)	3 (4.7%)	0 (0.0%)	64 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	2 (2.6%)	0 (0.0%)	0 (0.0%)	2 (2.6%)
		Normal	1 (1.3%)	65 (84.4%)	5 (6.5%)	1 (1.3%)	72 (93.5%)
		High	0 (0.0%)	2 (2.6%)	1 (1.3%)	0 (0.0%)	3 (3.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.3%)	69 (89.6%)	6 (7.8%)	1 (1.3%)	77 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	5 (6.8%)	62 (84.9%)	3 (4.1%)	0 (0.0%)	70 (95.9%)
		High	0 (0.0%)	1 (1.4%)	2 (2.7%)	0 (0.0%)	3 (4.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	5 (6.8%)	63 (86.3%)	5 (6.8%)	0 (0.0%)	73 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 32	Placebo	Low	1 (1.6%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	2 (3.2%)
		Normal	0 (0.0%)	50 (80.6%)	3 (4.8%)	0 (0.0%)	53 (85.5%)
		High	0 (0.0%)	2 (3.2%)	5 (8.1%)	0 (0.0%)	7 (11.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	53 (85.5%)	8 (12.9%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (1.8%)	49 (87.5%)	2 (3.6%)	0 (0.0%)	52 (92.9%)
		High	0 (0.0%)	3 (5.4%)	1 (1.8%)	0 (0.0%)	4 (7.1%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.8%)	52 (92.9%)	3 (5.4%)	0 (0.0%)	56 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	2 (2.8%)
		Normal	0 (0.0%)	61 (84.7%)	1 (1.4%)	1 (1.4%)	63 (87.5%)
		High	0 (0.0%)	2 (2.8%)	5 (6.9%)	0 (0.0%)	7 (9.7%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	64 (88.9%)	6 (8.3%)	1 (1.4%)	72 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (3.1%)
		Normal	3 (4.6%)	52 (80.0%)	0 (0.0%)	0 (0.0%)	55 (84.6%)
		High	0 (0.0%)	4 (6.2%)	4 (6.2%)	0 (0.0%)	8 (12.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	4 (6.2%)	57 (87.7%)	4 (6.2%)	0 (0.0%)	65 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Week 40	Placebo	Low	0 (0.0%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	1 (1.6%)
		Normal	1 (1.6%)	51 (82.3%)	5 (8.1%)	0 (0.0%)	57 (91.9%)
		High	0 (0.0%)	1 (1.6%)	3 (4.8%)	0 (0.0%)	4 (6.5%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.6%)	53 (85.5%)	8 (12.9%)	0 (0.0%)	62 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
		Normal	0 (0.0%)	47 (85.5%)	1 (1.8%)	0 (0.0%)	48 (87.3%)
		High	0 (0.0%)	4 (7.3%)	2 (3.6%)	0 (0.0%)	6 (10.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	52 (94.5%)	3 (5.5%)	0 (0.0%)	55 (100.0%)
	Omalizumab 150mg	Low	1 (1.4%)	3 (4.3%)	0 (0.0%)	0 (0.0%)	4 (5.7%)
		Normal	0 (0.0%)	62 (88.6%)	1 (1.4%)	1 (1.4%)	64 (91.4%)
		High	0 (0.0%)	0 (0.0%)	2 (2.9%)	0 (0.0%)	2 (2.9%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (1.4%)	65 (92.9%)	3 (4.3%)	1 (1.4%)	70 (100.0%)
	Omalizumab 300mg	Low	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)	2 (2.9%)
		Normal	2 (2.9%)	54 (79.4%)	2 (2.9%)	0 (0.0%)	58 (85.3%)
		High	0 (0.0%)	5 (7.4%)	3 (4.4%)	0 (0.0%)	8 (11.8%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	3 (4.4%)	60 (88.2%)	5 (7.4%)	0 (0.0%)	68 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
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Table 14.3/29
Laboratory Abnormalities by Visit and Baseline Status
Safety Evaluable Patients

Laboratory Parameter: Neutrophils Absolute Count (x10^9/L)

Visit	Treatment Group		Baseline: Low	Baseline: Normal	Baseline: High	Baseline: Missing	Baseline: Total
Early Term	Placebo	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	9 (90.0%)	0 (0.0%)	0 (0.0%)	9 (90.0%)
		High	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (100.0%)	0 (0.0%)	0 (0.0%)	10 (100.0%)
	Omalizumab 75mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	4 (66.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
		High	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	5 (83.3%)	1 (16.7%)	0 (0.0%)	6 (100.0%)
	Omalizumab 150mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	0 (0.0%)	10 (83.3%)	1 (8.3%)	0 (0.0%)	11 (91.7%)
		High	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	1 (8.3%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	0 (0.0%)	10 (83.3%)	2 (16.7%)	0 (0.0%)	12 (100.0%)
	Omalizumab 300mg	Low	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Normal	1 (12.5%)	4 (50.0%)	1 (12.5%)	0 (0.0%)	6 (75.0%)
		High	0 (0.0%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	2 (25.0%)
		Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Total	1 (12.5%)	5 (62.5%)	2 (25.0%)	0 (0.0%)	8 (100.0%)

Lab abnormalities are based on the central laboratory normal ranges. Table entries provide the number of patients at the specified visit with the abnormality indicated in the first column, among patients with a baseline value as indicated in the second column. Baseline is defined as the patient's last available observation prior to the first administration of study drug for the treatment period (Day 1). Patients with missing baseline are included in the total row.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_lab_abnorm)
Database (CLOSED) Datasets (labv)
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Table 14.3/27.1
Baseline Serum Chemistry Values
Safety Evaluable Patients

Laboratory Parameter	Treatment Group	n	Mean	SD	Median	Minimum	Maximum
Sodium (mmol/L)	Placebo	79	141.2	2.6	141.0	136.0	154.0
	Omalizumab 75mg	70	140.8	2.2	141.0	136.0	146.0
	Omalizumab 150mg	85	141.1	2.4	141.0	136.0	147.0
	Omalizumab 300mg	81	140.7	2.6	141.0	134.0	149.0
Potassium (mmol/L)	Placebo	79	4.2	0.3	4.2	3.6	5.6
	Omalizumab 75mg	70	4.3	0.4	4.2	3.4	6.5
	Omalizumab 150mg	85	4.3	0.3	4.2	3.6	5.5
	Omalizumab 300mg	81	4.4	0.4	4.4	3.2	5.6
Glucose (mmol/L)	Placebo	79	5.4	1.1	5.1	3.4	10.5
	Omalizumab 75mg	70	5.4	1.8	5.0	3.3	15.9
	Omalizumab 150mg	85	5.3	1.1	5.1	3.6	11.0
	Omalizumab 300mg	80	5.2	0.8	5.0	3.8	9.8
Protein Albumin (g/L)	Placebo	79	40.0	3.4	40.0	33.0	48.0
	Omalizumab 75mg	70	40.2	3.4	40.0	31.0	49.0
	Omalizumab 150mg	85	39.9	3.2	40.0	29.0	48.0
	Omalizumab 300mg	81	39.8	3.1	40.0	33.0	47.0
SGOT/AST (U/L)	Placebo	79	20.9	7.5	20.0	11.0	54.0
	Omalizumab 75mg	70	21.9	7.4	21.0	11.0	64.0
	Omalizumab 150mg	84	20.4	6.0	19.0	12.0	49.0
	Omalizumab 300mg	80	21.2	5.8	20.0	7.0	44.0
SGPT/ALT (U/L)	Placebo	79	22.3	16.0	18.0	8.0	96.0
	Omalizumab 75mg	70	23.2	11.7	20.0	9.0	76.0
	Omalizumab 150mg	85	20.0	8.9	17.0	9.0	49.0
	Omalizumab 300mg	81	19.7	6.7	19.0	10.0	47.0
Chloride (mmol/L)	Placebo	79	104.0	2.6	104.0	98.0	112.0
	Omalizumab 75mg	70	103.3	2.5	104.0	95.0	108.0
	Omalizumab 150mg	85	103.4	2.4	103.0	98.0	110.0
	Omalizumab 300mg	81	103.0	2.4	103.0	96.0	109.0

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_serumchem)
Database (CLOSED) Datasets (labv)
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Table 14.3/27.2
Baseline Urinalysis
Safety Evaluable Patients

	Placebo (n=80)	Omalizumab 75mg (n=70)	Omalizumab 150mg (n=87)	Omalizumab 300mg (n=81)	All Subjects (n=318)
Urine Protein					
n	79	70	85	81	315
Negative	60 (75.9%)	47 (67.1%)	65 (76.5%)	63 (77.8%)	235 (74.6%)
Trace	14 (17.7%)	19 (27.1%)	17 (20.0%)	13 (16.0%)	63 (20.0%)
1+ and above	5 (6.3%)	4 (5.7%)	3 (3.5%)	5 (6.2%)	17 (5.4%)
Urine Glucose					
n	79	70	85	81	315
Trace	(0.0%)	1 (1.4%)	(0.0%)	(0.0%)	1 (0.3%)
Normal	79 (100.0%)	68 (97.1%)	84 (98.8%)	80 (98.8%)	311 (98.7%)
1+ and above	(0.0%)	1 (1.4%)	1 (1.2%)	1 (1.2%)	3 (1.0%)
Urine Ketones					
n	79	70	85	81	315
Negative	78 (98.7%)	67 (95.7%)	82 (96.5%)	78 (96.3%)	305 (96.8%)
Trace	1 (1.3%)	1 (1.4%)	2 (2.4%)	1 (1.2%)	5 (1.6%)
1+ and above	(0.0%)	2 (2.9%)	1 (1.2%)	2 (2.5%)	5 (1.6%)
Urine Specific Gravity					
n	79	70	85	81	315
Normal	78 (98.7%)	70 (100.0%)	85 (100.0%)	80 (98.8%)	313 (99.4%)
Low	1 (1.3%)	(0.0%)	(0.0%)	(0.0%)	1 (0.3%)
High	(0.0%)	(0.0%)	(0.0%)	1 (1.2%)	1 (0.3%)
Urine Red Blood Cell					
n	28	32	27	28	115
1 - 5/HPF	27 (96.4%)	29 (90.6%)	26 (96.3%)	28 (100.0%)	110 (95.7%)
6 - 20/HPF	1 (3.6%)	1 (3.1%)	1 (3.7%)	(0.0%)	3 (2.6%)
+20/HPF	(0.0%)	2 (6.3%)	(0.0%)	(0.0%)	2 (1.7%)
Urine White Blood Cell					
n	48	39	54	50	191
1 - 5/HPF	41 (85.4%)	37 (94.9%)	50 (92.6%)	40 (80.0%)	168 (88.0%)
6 - 20/HPF	7 (14.6%)	(0.0%)	2 (3.7%)	7 (14.0%)	16 (8.4%)
+20/HPF	(0.0%)	2 (5.1%)	2 (3.7%)	3 (6.0%)	7 (3.7%)

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_urine)
Database (CLOSED) Datasets (pat labv)
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Table 14.3/30
Anti-Therapeutic Antibodies
Safety Evaluable Patients

Serum Antibody(ATA)	Visit	Results	Placebo (N=80)	Omalizumab 75 mg (N=70)	Omalizumab 150 mg (N=87)	Omalizumab 300 mg (N=81)
Anti-rhuFab	Day1 (Predose)	n	78	69	83	81
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	78(100%)	69(100%)	83(100%)	81(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)
	Week 40	n	62	56	69	66
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	62(100%)	56(100%)	69(100%)	66(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)
	Early Term	n	9	7	13	8
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	9(100%)	7(100%)	13(100%)	8(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)

For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_abconc_freq)
Database (CLOSED) Datasets (abconc)
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Table 14.3/30
Anti-Therapeutic Antibodies
Safety Evaluable Patients

Serum Antibody(ATA)	Visit	Results	Placebo (N=80)	Omalizumab 75 mg (N=70)	Omalizumab 150 mg (N=87)	Omalizumab 300 mg (N=81)
Anti-rhuFc	Day1 (Predose)	n	78	69	83	81
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	78(100%)	69(100%)	83(100%)	81(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)
	Week 40	n	62	56	69	66
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	62(100%)	56(100%)	69(100%)	66(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)
	Early Term	n	9	7	13	8
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
		Negative	9(100%)	7(100%)	13(100%)	8(100%)
		Missing	0(0%)	0(0%)	0(0%)	0(0%)

For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.

Table 14.3/30
Anti-Therapeutic Antibodies
Safety Evaluable Patients

Serum Antibody(ATA)	Visit	Results	Placebo (N=80)	Omalizumab 75 mg (N=70)	Omalizumab 150 mg (N=87)	Omalizumab 300 mg (N=81)
Both Anti-rhuFab and Anti-rhuFc	Day1 (Predose)	n	156	138	166	162
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
	Week 40	n	124	112	138	132
		Positive	0(0%)	0(0%)	0(0%)	0(0%)
	Early Term	n	18	14	26	16
		Positive	0(0%)	0(0%)	0(0%)	0(0%)

For patients who received open-label Omalizumab during the follow-up period, data collected on or after the date they received Omalizumab during the follow-up period were excluded from the analysis.

Source: Biostatistics([redacted] pgm(/allergy/E25/q4881g/final/programs/t_abconc_freq)
Database (CLOSED) Datasets (abconc)
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