

2.7.3. Summary of Clinical Efficacy

Tirzepatide (LY3298176)

Lilly Research Laboratories
Eli Lilly and Company
Indianapolis, Indiana, USA

Confidential Information

The information contained in this document is confidential. It is the property of Eli Lilly and Company or its subsidiaries and should not be copied by or distributed to persons not involved in the review of clinical investigations for tirzepatide (LY3298176), unless such persons are bound by a confidentiality agreement with Eli Lilly and Company or its subsidiaries.

Note to Regulatory Authorities: This document may contain protected personal data and/or commercially confidential information exempt from public disclosure. Eli Lilly and Company requests consultation regarding release/redaction prior to any public release. In the United States, this document is subject to Freedom of Information Act (FOIA) Exemption 4 and may not be reproduced or otherwise disseminated without the written approval of Eli Lilly and Company or its subsidiaries.

Document ID: VV-CLIN-109424

Table of Contents

Section	Page
2.7.3. Summary of Clinical Efficacy	1
2.7.3.1. Background and Overview of Clinical Efficacy	3
2.7.3.2. Summary of Results of Individual Studies	3
2.7.3.3. Comparison and Analyses of Results Across Studies.....	3
2.7.3.4. Analysis of Clinical Information Relevant to Dosing Recommendations	3
2.7.3.5. Persistence of Efficacy and/or Tolerance Effects	3

Summary of Clinical Efficacy

2.7.3.1. Background and Overview of Clinical Efficacy

This is a single-study submission comprised of one Phase 1 bioequivalence Study I8F-MC-GPIP (GPIP). As clinical efficacy was not an objective of Study GPIP, efficacy results are not included in this submission.

2.7.3.2. Summary of Results of Individual Studies

Study GPIP assessed the pharmacokinetics, safety, and tolerability of a 5-mg subcutaneous dose of tirzepatide preserved formulation administered via multi-dose prefilled pen (test) versus the non-preserved formulation administered via single-dose pen (reference).

Results are presented in the [GPIP](#) clinical study report.

2.7.3.3. Comparison and Analyses of Results Across Studies

Not applicable.

2.7.3.4. Analysis of Clinical Information Relevant to Dosing Recommendations

Not applicable.

2.7.3.5. Persistence of Efficacy and/or Tolerance Effects

Not applicable.