2.7.4. Summary of Clinical Safety

Tirzepatide (LY3298176)

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Document ID: VV-CLIN-116183

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Summary of Clinical Safety

This is a single study submission comprised of one Phase 1 bioequivalence Study I8F-MC-GPIP (GPIP) in healthy participants. This study assessed the pharmacokinetics, safety, and tolerability of a 5-mg subcutaneous dose of tirzepatide preserved formulation administered via fixed, multi-dose single-patient-use prefilled pen (multi-dose PFP; test) versus the non-preserved formulation administered via single-dose pen (SDP; reference).

2.7.4.1. Exposure to the Drug

Study drug exposure, participant demographics, and other characteristics are presented in the GPIP CSR.

2.7.4.2. Adverse Events

No deaths or serious adverse events were reported during the study. Administration of tirzepatide was generally well tolerated with a similar incidence of treatment-emergent adverse events (TEAEs) observed with multi-dose PFP and SDP delivery of tirzepatide. The most common TEAEs were gastrointestinal disorders consistent with the known safety profile of the glucagon-like peptide 1 receptor agonist class and established safety profile of tirzepatide.

Full safety data are presented in the GPIP CSR.

2.7.4.2.1. Narratives

Participant narratives are provided in the GPIP CSR.

2.7.4.3. Clinical Laboratory Evaluations

No trends or changes in clinical laboratory evaluations were considered to be clinically significant. Although some participants had values outside the reference range, the findings were generally transient and occurred at isolated time points. Details on clinical laboratory evaluations are provided in the GPIP CSR.

2.7.4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety

The analyses detected no clinically meaningful trends in the vital sign measurements in this study. Details on vital signs and other safety evaluations are provided in the GPIP CSR.

2.7.4.5. Safety in Special Groups and Situations

Not applicable.

2.7.4.6. Postmarketing Data

Not applicable.