2.7.3. Summary of Clinical Efficacy

Tirzepatide (LY3298176)

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Document ID: VV-CLIN-109424

Approved on 11 Sep 2023 GMT

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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.