Lilly

J1I-MC-GZBO

TRIUMPH-OUTCOMES

elixia

Title:

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Event-Driven Study to Investigate the Effect of Retatrutide on the Incidence of Major Adverse Cardiovascular Events and the Decline in Kidney Function in Participants with Body Mass Index ≥27 kg/m2 and Atherosclerotic Cardiovascular Disease and/or Chronic Kidney Disease

Overview

Approximately 10,000 participants will be randomly assigned (1:1 ratio) to receive either retatrutide or placebo added to their existing standard of care background medications. Participants will administer their retatrutide or placebo dose once weekly by subcutaneous injection using a single-dose pen.

The purpose of this study is to determine if retatrutide is superior to placebo on the reduction of major adverse cardiovascular events and/or kidney outcomes in participants with body mass index ≥27 kg/m2 and ASCVD and/or chronic kidney disease.

Study Indication:

Subject with □ BMI >27.0 kg/m2. □ individuals ≥45 years of age who have established ASCVD and/or CKD.

Objectives & Endpoints

To demonstrate whether Retatrutide QW is superior to placebo in adults with BMI ≥27 kg/m2 and ASCVD and/or CKD in reducing the risk for major cardiovascular events and reducing the risk for kidney outcomes (including CV death)

Study Compensation:

Compensation varies with range from $140 to $56 per visit depends on type of visit and duration of stay at site or remote visit. Subject will also receive Travel Reimbursement.

Study Duration:

The mean treatment duration is anticipated to be approximately 3.3 years until at least 1296 participants experience at least 1 CV component and until at least 1085 participants experience at least 1 kidney event of the primary kidney composite endpoint

Investigational Product:

Retatrutide is a novel synthetic molecule, which shows potent agonist action at the GIP receptor, GLP-1 receptor, and glucagon receptor and has the clinically meaningful improvements in long-term outcomes associated with obesity.

The proposed Study GZBO is designed to characterize the effect of Retatrutide on cardiovascular outcomes, kidney outcomes, and kidney function.

Major Eligibility Criteria:

Major Inclusion Criteria:

- BMI >27.0 kg/m2
- Men or Women; ≥45 years of age
- Established ASCVD and/or CKD
  - a) Coronary artery disease
    OR
  - b) Cerebrovascular disease
    OR
  - c) Peripheral arterial disease
    OR
  - d) Chronic kidney disease diagnosis with
    - eGFR <45 mL/min/1.73 m2 and UACR >30 mg/g
    - eGFR <60 mL/min/1.73 m2 and UACR >100 mg/g
    - eGFR <75 mL/min/1.73 m2 and UACR >300 mg/g

Major Exclusion Criteria:

- Type 1 Diabetes or diabetic ketoacidosis or Severe Hypoglycemia
- Treatment like steroids, focal/grid macular laser surgery, anretinal photocoagulation, or vitrectomy for diabetic retinopathy
- Any CV conditions e.g, Acute MI, ACS, Stroke etc
- Acute Decompensated Heart Failure
- NYHA Functional Classification Class IV heart failure
- eGFR (CKD-epi-cystatin c equation) <20 mL/min/1.73 m2
- UACR >5000 mg/g
- Any dialysis ≤90 days
- Any Obesity relate procedure e.g., liposuction
- Chronic or Acute Pancreatitis.
- Multiple Endocrine Neoplasia Syndrome Type 2.
- Acute or Chronic Hepatitis
- History of malignant neoplasms ≤5 years or solid organ transplant