

ForPatients

by Roche

Obesity

A Study to Evaluate the Effects of Enicepatide in Participants With Obesity or Overweight, With or Without Type 2 Diabetes

Trial Status
Recruiting

Trial Runs In
1 Country

Trial Identifier
NCT07670416 YC46401

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Once-Weekly RO7795068 in Adult Chinese Patients With Obesity or Overweight, With or Without Type 2 Diabetes Mellitus

Trial Summary:

The purpose of this study is to assess the efficacy and safety of enicepatide, a dual glucagon-like peptide-1 (GLP-1)/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (RA) being developed for chronic weight management, as an adjunct to a reduced-calorie diet and increased physical activity in participants without Type 2 diabetes mellitus (T2DM) who have obesity or overweight with at least one weight-related comorbidity, and in participants with T2DM who have obesity or overweight.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT07670416 YC46401
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Body mass index (BMI) #24.0 kilograms per meter squared (kg/m²) for participants with type 2 diabetes mellitus (T2DM)

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- BMI ≥ 28.0 kg/m² or BMI ≥ 24.0 and < 28.0 kg/m² and diagnosed with at least one weight-related comorbidity (prediabetes, hypertension, dyslipidemia, fatty liver, obstructive sleep apnea, or weight-related cardiovascular disease) for participants without T2DM
- Agreement to adhere to the contraception requirements

Exclusion Criteria:

- History of Type 1 diabetes mellitus (T1DM)
- Obesity induced by other endocrinologic disorders
- Any planned major medical procedure or surgery during the study
- History of significant active or unstable major depressive disorder (MDD) or other severe psychiatric disorder
- Any lifetime history of suicide attempt
- History of any hematologic conditions that may interfere with HbA1c measurement
- History of acute or chronic pancreatitis or clinically significant gallbladder disease
- Treatment with any approved or investigational GLP-1-RA-based therapy within 6 months prior to randomization
- Treatment with other investigational therapy within 3 months prior to randomization or less than 5 elimination half-lives prior to randomization, whichever is longer
- Known allergy to any component of the study drug formulation or any other condition that is a contraindication to GLP-1 RAs or GLP-1/GIP RAs