ForPatients
by Roche

Healthy Volunteers

A Study to Assess the Effect of Subcutaneous Injection Site on the Pharmacokinetics of Pegozafermin in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07835243 GP46978

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 1, Open-Label, Randomized, Single-Dose Study to Evaluate the Effect of Subcutaneous Injection Site on the Pharmacokinetics of Pegozafermin in Healthy Participants

Trial Summary:

The purpose of this study is to evaluate the pharmacokinetics (PK) of a single subcutaneous (SC) dose of pegozafermin administered in the abdomen, thigh, or upper arm in healthy participants.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT07835243 GP46978
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 65 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Participants with a body mass index (BMI) within the range of 18.5-35.0 kilogram per square meter (kg/m^2)
- Participants in good health, as determined by medical history, physical examination findings, vital signs, electrocardiogram (ECG), and clinical laboratory tests at screening and prior to dosing
- Participants with willingness and ability to comply with all study requirements

Exclusion Criteria:

- Participants with a history of pancreatitis or gallbladder/biliary disorders (including cholelithiasis or cholecystitis), clinically significant menstrual abnormalities per investigator judgment, or hypertension
- Participants with known hypersensitivity to pegozafermin or its excipients or history of severe allergic or hypersensitivity reactions that may place the participant at risk
- Participants with any abnormality of the skin such as tattoo(s) or scarring or SC tissue at or near potential injection sites that may interfere with administration or assessment of the injection
- Participants with any history of malignancy
- Participants who are pregnant, breastfeeding, or planning to become pregnant during the study or within the timeframe in which contraception is required
- Participants with a positive result for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV)-1 or HIV-2 antibodies or p24 antigen at screening
- Participants with significant alcohol consumption, defined as > 14 units/week for females or > 21 units/week for males
- Participants with a history of recent (i.e., 6 months) bone trauma, fracture, or surgery or other clinically significant bone-related conditions
- Participants with poor peripheral venous access

Note: Other protocol-defined inclusion/exclusion criteria may apply.