ForPatients
by Roche

Healthy Volunteers

A Study to Evaluate the Effect of Injection Site on PK of Astegolimab in Healthy Subjects

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06462118 GP45400

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 Injection Site on the Pharmacokinetics of Astegolimab in Healthy Subjects

Trial Summary:

The main objective is to study how astegolimab may behave in the body when injected subcutaneously into the abdomen, thigh, or upper arm in healthy participants.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT06462118 GP45400
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 55 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Body weight of #50 kg to #110 kg with body mass index (BMI) range 18.0 to 30.0 kg/m2 (inclusive) at screening

Exclusion Criteria:

- History of significant hypersensitivity or severe allergic reaction, including anaphylaxis, to any drug compound, food, or other substance

- Any immunization or vaccination 14 days prior to the Check-in (Day -1) or plans to obtain any immunization or vaccination within 30 days after the Check-in
- Any surgical procedure (except for minor surgeries) within 28 days prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- Donation of blood from 30 days prior to screening through study completion or end of trial, inclusive, or of plasma from 2 weeks prior to screening through study completion or end of trial, inclusive
- History of immunodeficiency, including but not limited to, human immunodeficiency virus (HIV) infection
- History of active or untreated latent tuberculosis
- History of malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer
- Unstable cardiac disease, myocardial infarction, or New York Heart Association Class 3 or 4 heart failure within 12 months prior to screening
- History or presence of clinically significant ECG abnormalities at screening or check-in (Day -1)
- Positive for Hepatitis B or Hepatitis C (HCV)
- Tattoo(s) or scarring at or near the site of injection (abdomen, front and middle thigh, or upper arm) or any other condition which may interfere with the injection site examination (as determined by the Investigator)