ForPatients
by Roche

Atherosclerosis

A Study to Evaluate the Efficacy, Safety, Pharmacodynamics (PD), and Pharmacokinetics (PK) of Selnoflast in Reducing Vascular Inflammation in Participants With Atherosclerosis at Risk for Major Adverse Cardiac Events

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07448038 GC46102

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 IIa, Multicenter, Randomized, Double-blind, Placebo-controlled Study of the Efficacy, Safety, Pharmacodynamics, and Pharmacokinetics of Selnoflast in Reducing Vascular Inflammation in Patients With Atherosclerosis at Risk for Major Adverse Cardiac Events

Trial Summary:

The main purpose of the study is to evaluate the efficacy of selnoflast compared with placebo in participants with atherosclerosis, at high-risk for major adverse cardiovascular event (MACE), who are currently on standard-of-care (SOC) therapy.

Genentech, Inc.	Phase 2
Sponsor	Phase

NCT07448038 GC46102
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 80 Years	No

Inclusion Criteria:

- Confirmed evidence of atherosclerosis
- Left or right carotid TBR # 1.8 or aorta TBR # 2.0 on centrally-assessed 18F-fluorodeoxyglucose-Positron Emission Tomography (18F-FDG-PET) scan

- Stable treatment of atherosclerosis through the use of SOC medications or revascularization
- QT interval corrected through use of Fridericia's formula (QTcF) of # 450 milliseconds (ms) in men and # 470 ms in women by a single 12-lead electrocardiogram (ECG) recording

Exclusion Criteria:

- Individuals with Class III and IV heart failure
- Uncontrolled cardiac arrhythmia
- Uncontrolled hypertension
- Suspected or known immunocompromised state
- Planned procedure or surgery during the study and any major surgery within 90 days prior to screening Visit 1
- 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
- Positive test results for hepatitis B (HBV) infection at screening
- Positive hepatitis C virus (HCV) antibody test at screening
- Positive human immunodeficiency virus (HIV) test at screening
- Treatment with any live vaccine within 28 days prior to the first dose of study drug until the end of the study
- Treatment with other non-live vaccines within 14 days prior to the first dose of study drug until the end of the study