

Diabetic Macular Edema

A Study to Investigate the Safety, Tolerability, Pharmacokinetics (PK) and Pharmacodynamics (PD) of RO7497372 in Participants With Diabetic Macular Edema (DME)

Trial Status
Recruiting

Trial Runs In
2 Countries

Trial Identifier
NCT06847854 BP44175

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 I, Multipart, Multicenter Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of RO7497372 Following Intravitreal Administration in Participants With Diabetic Macular Edema (Part 1 Non-Randomized, Open-Label, Multiple Ascending Dose; Part 2 Randomized, Double-Masked)

Trial Summary:

This study will assess the safety and tolerability of RO7497372 in participants with DME. The study consists of 2 parts. Part 1 will test multiple-ascending doses of RO7497372 after unilateral intravitreal (IVT) administration in participants with DME. The main purpose of Part 1 is to provide data for RO7497372 safety and tolerability, as well as to characterize the ocular and systemic pharmacokinetics (PK), systemic anti-drug antibodies (ADA), and duration of target engagement, i.e., the pharmacodynamics (PD) in aqueous humor (AH) and blood. Part 2 will evaluate the safety, tolerability, PK, and PD of two dose strengths of RO7497372 (low dose and high dose), identified as safe and tolerated in Part 1.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT06847854 BP44175
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2), as defined by the world health organization (WHO) and/or American Diabetes Association
- Participant consents to AH collection
- Collection of > 90 microlitres (µL) AH (at each visit required per schedule of activities [SoA]) if deemed feasible and safe by the Investigator.
- Macular thickening secondary to DME involving the center of the fovea with CST $\geq$ 325 µm at screening
- Decreased BCVA primarily due to DME with ETDRS score of 78 to 19 letters (both inclusive) at screening
- Adequately clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images
- Diagnosis of non-proliferative DR
- Treatment-naïve and Pre-treated participants after washout

Exclusion Criteria:

- Any major illness or major surgical procedure # 4 weeks before Day 1
- Any febrile illness and associated sequelae # 1 week prior to Day 1
- Active cancer # 1 year prior to Day 1
- Cerebral vascular accident (including stroke and transient ischemic attack) or myocardial infarction # 24 weeks prior to Day 1
- HbA1c # 12% at screening
- Any panretinal photocoagulation or macular laser photocoagulation treatment prior to Day 1
- History of vitreoretinal surgery/pars plana vitrectomy
- Any cataract surgery within 12 weeks prior to Day 1 or any planned surgery during the study
- History of any glaucoma surgery including laser glaucoma procedures
- Uncontrolled glaucoma
- Any active intra- or periocular infection on Day 1
- Any active or history of Intraocular inflammation
- Intravitreal treatment with an anti-IL-6 (e.g., vamorbutant) or anti-IL-6 receptor treatment at any time
- Any proliferative DR