ForPatients
by Roche

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	Trial Runs In	Trial Identifier
Recruiting	2 Countries	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.	Phase 1
Sponsor	Phase

NCT06847854 BP44175
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	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 >= 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-naive 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., vamikibart) or anti-IL-6 receptor treatment at any time
- Any proliferative DR