

Diabetic Macular Edema

**A Study to Evaluate the Safety, Tolerability, Pharmacodynamics,
and Pharmacokinetics of RO7823653 in Participants With Diabetic
Macular Edema (DME)**

Trial Status
Not yet recruiting

Trial Runs In

Trial Identifier
NCT07425522 GR46431

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, Multicenter, Open-Label, Multiple-Ascending Dose Study of the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of RO7823653 Administered by Intravitreal Injection as Monotherapy and in Combination With Faricimab in Patients With Diabetic Macular Edema

Trial Summary:

The purpose of this study is to evaluate the safety, tolerability, Pharmacodynamics (PD), and Pharmacokinetics (PK) of multiple doses of RO7823653 in participants with DME, administered by intravitreal (IVT) injection as monotherapy and co-administered with faricimab.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07425522 GR46431
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
- Glycated hemoglobin (HbA1c) \leq 12%

ForPatients

by Roche

- For study eye: Macular thickening secondary to DME involving the center of the fovea with central subfield thickness (CST) \geq 325 micrometers (μm) as measured by SD-OCT and BCVA of 65 to 35 letters

Exclusion Criteria:

- Currently untreated diabetes mellitus or previously untreated participants who initiated oral anti-diabetic medication or insulin within 90 days prior to Day 1
- Pregnant or breastfeeding, or intending to become pregnant during the study or within the timeframe in which contraception is required
- Uncontrolled blood pressure
- For Parts 1 and 2: Any history of ocular injection/implant therapy (e.g., anti-vascular endothelial growth factor agents (anti-VEGF), anti-VEGF/anti-angiopoietin-2 (Ang-2 agents), corticosteroids, device implant.
- For Part 3: History of treatment with any of the following: Aflibercept 2 mg, ranibizumab, bevacizumab, or anti-VEGF biosimilars within 90 days prior to Day 1; Aflibercept 8 mg, brolucizumab, or faricimab within 120 days prior to Day 1; Triamcinolone acetonide (IVT, suprachoroidal, or periorbital) within 120 days prior to Day 1; Dexamethasone intravitreal implant within 180 days prior to Day 1; Fluocinolone acetonide (FA) intravitreal implant within 3 years prior to Day 1; Device implant
- History of uveitis, vitritis (grade trace or above), and/or scleritis in either eye
- Active intraocular inflammation in either eye
- Any previously documented or current proliferative diabetic retinopathy (PDR) in the study eye