

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

NCT07425522

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1
<b>Sponsor</b>	Genentech, Inc.
<b>Enrollment</b>	93 participants

## Key Eligibility Criteria

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### Inclusion (3)

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

### Exclusion (8)

- 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 periocular) 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
- ... and 3 more (see full listing online)

## Locations (3 total)

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Associated Retina Consultants - Peoria - DocTrials - PPDS, Peoria, Arizona, United States  
Retina Research Institute of Texas, Abilene, Texas, United States  
Austin Clinical Research, LLC, Austin, Texas, United States