ForPatients
by Roche

Diabetic Macular Edema

A Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO7446603 Administered Alone or in Combination With Aflibercept or Faricimab in Participants With Diabetic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Recruiting	3 Countries	NCT06850922 ISRCTN14152148 GR43828

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/II Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO7446603 Administered Alone or in Combination With Aflibercept or Faricimab in Patients With Diabetic Macular Edema

Trial Summary:

This study aims to evaluate the ocular and systemic safety, tolerability and efficacy of RO7446603 in participants with diabetic macular edema (DME). The study consists of 2 segments: Phase I (Parts 1-4) and Phase II (Part 5). Phase I investigated the safety of RO7446603 following a single and multiple intravitreal (IVT) doses as monotherapy or co-administered with IVT aflibercept or IVT faricimab (in separate injections). Phase II will investigate the safety, tolerability, pharmacokinetics (PK) and efficacy of two dose levels of RO7446603 in combination with faricimab, with the two drugs co-mixed and administered as a single IVT injection, compared to faricimab alone. The first participant was enrolled in the Phase I segment on June 22, 2022. Phase I has been completed.

Genentech, Inc.
Sponsor

Phase 1/Phase 2
Phase

NCT06850922 ISRCTN14152148 GR43828
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#18 Years	No

Inclusion Criteria:

- Documented diagnosis of diabetes mellitus (DM) (Type 1 or Type 2) with glycated hemoglobin (HbA1c) < 12%
- Macular thickening secondary to DME involving the center of the fovea > 325 microns
- Decreased VA attributable primarily to DME between 25 and 73 ETDRS letters

Exclusion Criteria:

- Currently untreated DM or previously untreated participants who initiated oral anti-diabetic medication or insulin within 90 days prior to Day 1
- Uncontrolled blood pressure (BP)
- Pregnancy or breastfeeding, or intention to become pregnant during the study
- For Parts 1-4: IVT anti-VEGF treatment within 90 days prior to Day 1; For Part 5: IVT anti-VEGF treatment within 120 days prior to Day 1 or IVT anti-VEGF treatment prior to Day 1 for treatment naïve participants
- Treatment with SUSVIMOTM (ranibizumab injection) prior to Day 1
- Any IVT or periocular (sub-tenons) corticosteroid treatment within 6 months prior to Day 1
- Any current or history of ocular disease other than DME that may confound assessment of the macula or affect central vision
- Proliferative diabetic retinopathy (PDR) in the study eye
- Active or history of uveitis, vitritis (grade trace or above), and/or scleritis in either eye Other protocol-specified inclusion/exclusion criteria may apply