ForPatients
by Roche

Diabetic Macular EdemaUveitic Macular Edema

A Study to Investigate RO7200220 as Monotherapy and in Combination With Ranibizumab in Participants With Diabetic and Uveitic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT06771271 BP40899

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 Multi-center, Non-Randomized, Open-label, Multiple Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of RO7200220 in Monotherapy and in Combination With Ranibizumab Following Intravitreal Administration in Patients With Diabetic or Uveitic Macular Edema

Trial Summary:

The purpose of this study was to assess the safety and tolerability of RO7200220 as monotherapy (diabetic macular edema [DME] or uveitic macular edema [UME] population) and in combination with ranibizumab (DME population only).

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT06771271 BP40899
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

DME Participants:

- Diagnosis of Diabetes Mellitus (DM) (Type 1 or Type 2), as defined by the World Health Organization and/or American Diabetes Association

- Macular edema associated with DR defined as macular thickening by spectral domain optical coherence tomography (SD-OCT) involving the center of the macula: central subfield thickness (CST) of #325 µm with Spectralis.
- Decreased visual acuity (VA) attributable primarily to DME, with BCVA letter score of 73 to 19 letters (both inclusive) on Early Treatment Diabetic Retinopathy Study (ETDRS)-like charts (20/40 -20/400 Snellen equivalent).
- Clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images to confirm diagnosis.

UME Participants:

- Diagnosis of noninfectious uveitis (NIU) of any anatomical type (anterior, intermediate, posterior, panuveitis). Active and inactive NIU is allowed.
- Macular edema associated with NIU defined as macular thickening by SD-OCT involving the center of the macula: CST of #325 µm with Spectralis.
- Decreased VA attributable primarily to UME, with BCVA letter score of 78 to 19 letters (both inclusive) on ETDRS-like charts (20/32 - 20/400 Snellen equivalent).
- Sufficiently clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images to confirm diagnosis.
- Either treatment naive or previously treated in the study eye or systematically (with washout periods and maximum doses applicable for specific treatments).

Exclusion Criteria:

- Any major illness or major surgical procedure within 1 month prior to Day 1
- Any febrile illness within 1 week prior to screening or Day 1
- Any stroke or myocardial infarction within 12 months prior to Day 1
- Any active proliferative DR (DME participants only)
- Panretinal photocoagulation or macular laser photocoagulation treatment prior to Day 1
- History of vitreoretinal surgery/pars plana vitrectomy
- Any cataract surgery within 3 months prior to Day 1 or any planned surgery during the study
- History of any glaucoma surgery including laser glaucoma procedures
- Uncontrolled glaucoma
- History of rubeosis iridis
- Any active ocular or periocular infection on Day 1
- Any presence of active intraocular inflammation on Day 1 or any history of intraocular inflammation (DME participants only)
- Any prior or concomitant periocular or IVT corticosteroids in the study eye (DME treatment naive participants only)
- Use of any systemic corticosteroids within 1 month prior to Day 1 (stable oral prednisone for UME participants allowed)
- Any prior or concomitant systemic anti-VEGF treatment within 6 months prior to Day 1
- Any concurrent use of biologics for immune-related diseases