ForPatients
by Roche

Diabetic Macular Edema

A Study to Evaluate Efficacy, Safety & Pharmacokinetics of the Port Delivery System (PDS) With Ranibizumab in Participants With Diabetic Macular Edema (DME) Compared With Intravitreal Ranibizumab; A Subtudy to Evaluate the Safety of Re-Implanting the PDS With Ranibizumab in Participants With DME

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT04108156 GR40550

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 III, Multicenter, Randomized, Visual Assessor-Masked, Active-comparator Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System With Ranibizumab in Patients With Diabetic Macular Edema (Pagoda)

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of the PDS with Ranibizumab in participants with DME when treated every 24 weeks (Q24W) compared with intravitreal ranibizumab 0.5 mg every 4 weeks (Q4W). The substudy will evaluate the safety of re-implanting the updated PDS with ranibizumab and the refill-exchange procedures following re-implantation in participants with DME who were previously enrolled in the main Study, GR40550. Up to 100 participants from the main study will be enrolled and followed for a maximum of 72 weeks post-re-implantation in the substudy.
GR40550 Pagoda Re-Implantation Substudy Lay CTD 28Oct2024.pdf

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04108156 GR40550
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

ForPatients
by Roche

All	#18 Years	No

Inclusion Criteria:

- Age #18 years at time of signing Informed Consent Form
- Documented diagnosis of diabetes mellitus (Type 1 or Type 2)
- HbA1c level of #10% within 2 months prior to screening or at screening

Study eye

- Macular thickening secondary to DME involving the center of the fovea with CST #325 um on SD-OCT at screening
- BCVA score of 78 to 25 letters (20/32 to 20/320 approximate Snellen equivalent)
- Having experienced a septum dislodgement in the original implant while in the main study or after exiting the main study
- Sufficiently clear ocular media and adequate pupillary dilation to allow for analysis and grading by central reading center

Exclusion Criteria:

- High-risk proliferative diabetic retinopathy
- Active intraocular inflammation (grade trace or above)
- Suspected or active ocular or periocular infection of either eye
- Uncontrolled ocular hypertension or glaucoma and any such condition the investigator determines may require a glaucoma-filtering surgery during a patient's participation in the study
- Cerebrovascular accident or myocardial infarction within 6 months prior to randomization
- Atrial fibrillation diagnosis or worsening within 6 months prior to randomization
- Uncontrolled blood pressure

Substudy:

Exclusion Criteria (Cohort 1 Only):

- Recent history (in the last 3 months prior to enrollment) of other disease, other non-diabetic metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a condition that contraindicates the use of ranibizumab or surgical placement of the PDS implant; that might affect interpretation of the results of the study; or that renders the participant at high risk for treatment complications
- Active cancer within the last 12 months, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or prostate cancer
- Current systemic treatment for a confirmed active systemic infection
- Participation in an investigational trial that involves treatment with any drug or device (with the exception of vitamins and minerals or enrollment in Study GR40550) within 6 months prior to enrollment
- Use of antimitotic or antimetabolite therapy within 30 days

Ocular Exclusion Criteria for Study Eye:

- Any ocular condition that may render the participant at high risk for surgical or treatment complications
- Intraocular surgery (including cataract surgery) within 1 month preceding the enrollment visit

- Any use of medicated intraocular implants (other than the PDS implant), at any time prior to enrollment
- History of rhegmatogenous retinal tears or peripheral retinal breaks within 3 months prior to the enrollment visit
- Any concurrent ocular condition that would require surgical intervention during the study to prevent or treat visual loss
- Concurrent conjunctival, Tenon's capsule, and/or scleral condition in the supero-temporal quadrant of the eye (e.g., scarring, thinning, mass) that may affect the refill-exchange procedure of the PDS implant
- Ongoing ocular complications that might affect participant safety Ocular Exclusion Criteria for Either Eye
- Suspected or active ocular or periocular infection (e.g., infectious conjunctivitis or endophthalmitis)
- Any history of uveitis
- Active blepharitis