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 Substudy to Evaluate the Safety of Re-implanting the PDS With Ranibizumab in Participants With DME

NCT04108156

Status	RECRUITING
Phase	Phase 3
Sponsor	Hoffmann-La Roche
Enrollment	634 participants

Key Eligibility Criteria

Inclusion (8)

- Age e18 years at time of signing informed consent form (ICF)
- Documented diagnosis of diabetes mellitus (Type 1 or Type 2)
- Glycated haemoglobin (HbA1c) level of d10% within 2 months prior to screening or at screening
- Study eye
- Macular thickening secondary to DME involving the center of the fovea with CST e325 micrometer (µm) on SD-OCT at screening

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

Exclusion (22)

- High-risk PDR
- 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

... and 17 more (see full listing online)

Locations (92 total)

Barnet Dulaney Perkins Eye Center, Mesa, Arizona, United States
Retinal Consultants of Arizona;Opthalmology, Phoenix, Arizona, United States
Arizona Retina and Vitreous Consultants, Phoenix, Arizona, United States
... and 89 more locations