ForPatients
by Roche

Diabetic Macular Edema

A Study of RO6867461 in Participants With Center-involving Diabetic Macular Edema (BOULEVARD)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02699450 RG7716 BP30099

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 Multiple-Center, Multiple-Dose, Randomized, Active Comparator-Controlled, Double-Masked, Parallel Group, 36-Week Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO6867461 Administered Intravitreally in Patients With Diabetic Macular Edema

Trial Summary:

This is a multiple-center, multiple-dose, randomized, active comparator-controlled, double-masked, three parallel group, 36-week study in participants with center-involving diabetic macular edema (DME). Only one eye will be selected as the study eye. Where both eyes meet all eligibility criteria, the eye with the worse best corrected visual acuity (BCVA) will be defined as the study eye. The study will consist of a treatment period (20 weeks) and an observational period (up to 16 weeks). Treatment naive participants will be randomized in a 1:1:1 ratio to one of the Arms A, B and C, respectively. Participants previously treated with intravitreal (IVT) anti-vascular endothelial growth factor (VEGF) will be randomized in a 1:1 ratio to Arms A and C.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT02699450 RG7716 BP30099
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Macular edema associated with diabetic retinopathy
- Decreased visual acuity attributable primarily to DME
- Diagnosis of diabetes mellitus

Exclusion Criteria:

- High risk proliferative diabetic retinopathy
- Cataract surgery within 3 months of Baseline, or any other previous intraocular surgery
- Uncontrolled glaucoma
- Current or history of ocular disease in the study eye other than DME
- Major illness or major surgical procedure within 1 month prior to Day 1
- Uncontrolled blood pressure
- Glycosylated hemoglobin (HbA1c) greater than (>) 12 percent (%) at screening
- Untreated diabetes mellitus or initiation of oral anti-diabetic medication or insulin within 4 months prior to Day 1