KINGFISHER STUDY

For diabetic macular edema

Diabetic Macular Edema

12-Month, 2-Arm, Randomized, Double-Masked, Multicenter Phase III Study Assessing the Efficacy and Safety of Brolucizumab every 4 weeks versus Aflibercept every 4 weeks in Adult Patients with Visual Impairment due to Diabetic Macular Edema

Principal Investigator:
Matthew P. Ohr, MD

Inclusion Criteria:

- At least 18 years of age with type 1 or 2 diabetes mellitus and HbA1c ≤ 12% at screening
- Visual impairment of study eye due to DME with:
  - BCVA of 73 to 23 letters, inclusive (20/40 to 20/320 approximate Snellen equivalent)
  - Central Macular thickening secondary to DME with CSFT ≥ 320 μm on SD-OCT

Exclusion criteria

- High-risk PDR in the study eye
- Uncontrolled glaucoma
- IVT anti-VEGF treatment during the 3-month period prior to baseline
- Intraocular surgery or laser photocoagulation (macular or panretinal) during the 3-month period prior to baseline
- Any active intraocular or periocular infection or active intraocular inflammation
- Stroke or myocardial infarction during the 6-month period prior to baseline
- Uncontrolled blood pressure (defined as systolic ≥180 mmHg and/or diastolic ≥ 100 mmHg while a patient is at rest)

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