

A Study to Test Whether BI 1815368 Helps People With an Eye Condition Called Diabetic Macular Edema

NCT06962839

Status	RECRUITING
Phase	Phase 2
Sponsor	Boehringer Ingelheim
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (3)

- e18years of age
- Diagnosis of diabetes mellitus (DM) (type 1 or type 2), Haemoglobin A1C (HbA1c) \<12% treated with stable medication for at least 30 days prior to Day 1; no already-set plans for major changes in DM medication (e.g. start of new medication) at the time of screening and baseline
- Centre-involved diabetic macular edema (CI-DME) confirmed on spectral domain optical coherence tomography (SD-OCT) with central subfield foveal thickness (CST) e320 µm in the study eye at screening

Exclusion (5)

- Macular edema considered to be due to other causes than CI-DME in the study eye
- Proliferative diabetic retinopathy or iris neovascularisation (including the anterior chamber angle) in the study eye
- Any intravitreal (IVT) anti-vascular endothelial growth factor (VEGF) treatment within 4 months before Day 1 (other than faricimab or aflibercept 8mg), and within 6 months before Day 1 for faricimab or aflibercept 8 mg, and/or more than 4 prior IVT injections with anti-VEGF treatment in total in the study eye
- Any history of panretinal photocoagulation, macular laser photocoagulation, vitreoretinal surgery, IVT or periocular corticosteroid treatment (within 12 months before Day 1), history of fluocinolone ophthalmic implant or dexamethasone IVT implant before Day 1, or topical steroid or NSAID treatment (within 30 days before Day 1)
- Active ocular inflammation of any history of intraocular inflammation within 1 year

Locations (80 total)

Win Retina, Arcadia, California, United States
Retina Associates of Southern California, Huntington Beach, California, United States
Retinal Consultants Medical Group, Inc, Modesto, California, United States
... and 77 more locations

<https://clinicaltrials.gov/study/NCT06962839>

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