A Study to Evaluate the Efficacy and Safety of OTX-TKI (Axitinib Implant) in Participants With Non-Proliferative Diabetic Retinopathy

NCT07235085

Status	RECRUITING
Phase	Phase 3
Sponsor	Ocular Therapeutix, Inc.
Enrollment	930 participants

Key Eligibility Criteria

Inclusion (5)

- Male or female who is at least 18 years of age at the time of signing the informed consent form (ICF)
- History of or newly diagnosed with type 1 or 2 diabetes mellitus and have moderately severe to severe NPDR (DRSS levels 47 or 53), confirmed by the Central Reading Center (CRC) based on the images obtained at the Screening visit
- BCVA Early Treatment Diabetic Retinopathy Study (ETDRS) letter score of e 69 letters (approximate Snellen equivalent of 20/40 or better) in the study eye
- Willing and able to comply with clinic visits and study-related procedures
- Provide signed informed consent

Exclusion (4)

- Presence of center-involved diabetic macular edema (CI-DME) defined per protocol via optical coherence tomography (SD-OCT) in the study eye, obtained at the Screening visit
- Evidence of a rhegmatogenous retinal detachment or visually significant/severe epiretinal membrane, vitreomacular traction syndrome, macular hole, tear of the retinal pigment epithelium in the macula, or other macular pathology in the study eye deemed visually significant by the Investigator
- In the study eye, any panretinal photocoagulation (PRP) treatment prior to baseline, or received focal or grid laser photocoagulation within 1000 microns of the central subfield of the macula within 6 months prior to baseline
- IVT anti-VEGF treatment in the study eye within 6 months or port delivery system (PDS) with ranibizumab in the study eye at any time prior to baseline (Day 1)

Locations (1 total)

Cumberland Valley Retina Consultants, Hagerstown, Maryland, United States