# Diabetic Macular Edema

## About The Study:

Sponsored by KalVista Pharmaceutical, the purpose of this study is to evaluate the efficacy, safety, and tolerability of an investigational drug named, KVD001, as monotherapy in adult subjects with ciDME who have had prior anti-VEGF treatment

All participants will be randomized to one of three study groups:

- **Group A**—Sham injections every 4 weeks
- **Group B**—Lower dose (3µg) of study drug administered by intravitreal injection every 4 weeks, 4 injections total
- **Group C**—Higher dose (6 µg) of study drug administered by intravitreal injection every 4 weeks, 4 injections total

Participants participating in this study will make up to 8 scheduled study visits and 3 telephone calls over a period of 24 weeks. Each visit will last anywhere from 2-5 hours.

## Key Inclusion Criteria:

- Presence of ciDME in the study eye
- BCVA of ~20/40 or worse in the study eye
- First anti-VEGF injection in the study eye occurred ≤ 24 months ago
- Last anti-VEGF injection in the study is ≥ 8 weeks ago

## Key Exclusion Criteria:

- Current active proliferative diabetic retinopathy (PDR), active
- Prior treatment with panretinal photocoagulation or focal grid macular photocoagulation in the study eye within the previous 3 months
- Prior treatment with topical NSAIDs or topical steroids in the study eye within 1 month
- Prior vitrectomy in the study eye
- Intraocular pressure > 22mmHg or use of > 2 antiglaucoma agents in the study eye
- Poorly controlled DM defined as HgA1c ≥ 12.0%

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### For Additional Information Or To Refer A Patient, Contact:

Principal Investigator: Yevgeniy Shildkrot, MD
Study Coordinators: Ashton Leone, MPH, CCRP at (434) 243-5737 or aml7q@virginia.edu
Tamika Mercer, COA at (434) 243-2852 or tmm2v@virginia.edu
Allison Weiderhold at (434) 243-2921 or alw5rm@virginia.edu