Macular Edema Secondary To Retinal Vein Occlusion

About The Study:

Sponsored by Taiwan Liposome Company, the purpose of this multi-center study, called TLC399, is to assess the safety and efficacy of TLC399 (ProDex) in patients with macular edema due to retinal vein occlusion. TLC399 is a mixture of two agents. One is dexamethasone sodium phosphate (DSP) and the other is phospholipid (PL).

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

- **Group A**—0.36 mg dexamethasone sodium phosphate (DSP) with 100 mM phospholipid (PL)
- **Group B**—0.6 mg dexamethasone sodium phosphate (DSP) with 100 mM phospholipid (PL)
- **Group C**—0.6 mg dexamethasone sodium phosphate (DSP) with 50mM phospholipid (PL)

Participants participating in this study will have approximately 12 scheduled study visits over a period of 12 months. Each visit will last about 1-3 hours.

Key Inclusion Criteria:

- Age ≥ 18 years
- Confirmed macular edema due to CRVO or BRVO diagnosed within 12 months prior
- BCVA of 20/40 to 20/400 in the study eye

Key Exclusion Criteria:

- History of diabetic retinopathy in the study eye
- History of uncontrolled glaucoma (IOP ≥ 22 mm Hg)
- BCVA worse than 20/200 in the non-study eye
- Use of systemic steroids within 1 month of screening

For Additional Information Or To Refer A Patient, Contact:

Principal Investigator: Yevgeny 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