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STERLINGVISION

December 2, 2021

Hi. I'm writing to invite you and your patients to participate in a clinical trial using fenofibrate to prevent progression of diabetic retinopathy. The study is funded by the National Eye Institute.

You're probably aware of the FIELD and ACCORD-Eye studies showing that oral treatment with the PPARα agonist fenofibrate reduced progression of diabetic retinopathy. For copies of these and related articles, please scan the QR code above.

Treatment with fenofibrate for this indication has not been broadly adopted by the medical community. The reasons appear to be lack of familiarity with using fenofibrate and the desire for additional evidence of efficacy.

The clinical trial (Protocol AF) is designed to address those two concerns:

- A study specifically focused on diabetic retinopathy outcomes of oral fenofibrate. This will address limitations of previous studies.
- Determine the feasibility of a patient care model for ophthalmologists to prescribe fenofibrate or collaborate with the patient's diabetic care team.

Protocol AF provides benefits to your patients including a continuous glucose monitoring (CGM) device, study medications, ocular examinations, and laboratory safety studies.

Enrollment criteria are listed on the back of this letter.

To have a patient considered for a study, you may refer to me for management of diabetic retinopathy or contact our research team by phone (541-762-2763) or Email (help@verumresearch.com).

Sincerely,

Albert O. Edwards

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Title	A Randomized Clinical Trial Evaluating Fenofibrate for Prevention of Diabetic Retinopathy Worsening (Protocol AF)
Study Purpose	To evaluate the efficacy of oral Fenofibrate in preventing diabetic retinopathy (DR) worsening or development of CI-DME with vision loss in participants with mild to moderately severe non-proliferative DR and no CI-DME at baseline
Funding	National Eye Institute, NIH and others
Sponsor	Jaeb Center Diabetic Retinopathy Clinical Research (DRCR) Retina Network.
Principal Investigator	Albert O. Edwards, MD, PhD aedwards@oregonretina.org
Study Coordinator	Lillian Carroll lcarroll@oregonretina.org Clinic phone: 541-762-2763 Clinic Fax: 541-434-0912

Key Inclusion Criteria

- Age ≥ 18 year and < 80 years
- Type 1 or type 2 diabetes
- Willing to use a continuous glucose monitoring (CGM) device provided by study
- Ocular
    - Either (1) both eyes have mild to moderately severe NPDR or (2) one eye has mild to moderately severe NPDR and the other eye has microaneurysms only
    - Both eyes have BCVA of ≥ 79 (20/25 or better)

Key Exclusion Criteria

- HbA1c consistently above 11.0%
- Initiation of intensive insulin treatment (a pump or multiple daily injections) within 3 months prior to screening or necessary in next 3 months
- Decreased renal function, defined as requiring dialysis or central laboratory eGFR value < 60
- Blood pressure consistently above 160/100
- Use of coumadin anticoagulants
- Ocular
    - Current CI-DME in either eye or CST ≥ 305 µm in women or ≥ 320 µm in men
    - Any prior treatment for DME or DR in either eye