ShORe

A WET AMD CLINICAL STUDY

The ShORe Study

Dear Colleague,

We are currently recruiting for a Phase 3 randomized study for treatment-naïve neovascular age-related macular degeneration (nAMD) – the ShORe Study.

We would like to ask you for your help in referring any potential participants who might be eligible. Please feel free to discuss any information about the ShORe Study with your patients.

Why is the ShORe Study being done?

Age-related macular degeneration is a chronic degenerative eye disease of the central retina that causes progressive and severe loss of vision. Although the underlying etiology of nAMD is complex, it has been established that vascular endothelial growth factor (VEGF) plays a pivotal role. VEGF-A inhibitor therapies have revolutionized treatment of nAMD over the past 10 years. Despite significant gains or stabilization of vision, at least 45% of patients with nAMD exhibit some degree of resistance to VEGF-A inhibitor therapy. The investigational medication in this study targets VEGF-C and VEGF-D, which are critical mediators of blood vessel growth. The hope is that when the investigational medication is combined with a VEGF-A inhibitor, such as ranibizumab, there will be an improvement in vision over and above vision gains achieved with administration of a VEGF-A inhibitor alone.

The ShORe Study aims to determine the efficacy and safety of the investigational medication when administered in combination with intravitreal ranibizumab.

What will participation involve?

The ShORe Study will enroll approximately 990 participants and their participation will last for just under 2 years. The study will involve up to 27 study visits every 4 weeks and includes a screening period, treatment period, and follow-up period.

Eligible participants will be randomized 1:1:1 to 1 of 3 study groups:

- **Standard dosing:** Investigational medication and ranibizumab intravitreal injection every 4 weeks.
- **Extended dosing:** Investigational medication intravitreal injection every 4 weeks for the first 3 doses and then every 8 weeks, with a sham injection at the interim visits. Participants will also receive ranibizumab intravitreal injection once every 4 weeks.

- **Control:** Sham injection and ranibizumab intravitreal injection once every 4 weeks.

Eligibility criteria

Key inclusion criteria

- Male or female participants at least 50 years of age
- Active choroidal neovascularization (CNV) ≥50% lesion area, occult (<10 mm^2), predominantly classic, or minimally classic on fluorescein angiography
- An Early Treatment Diabetic Retinopathy Study best-corrected visual acuity (ETDRS BCVA) score between 60 and 25 (inclusive) letters

Key exclusion criteria

- Any previous treatment for nAMD, or previous treatment for CNV due to other causes, including, but not limited to, anti-VEGF-A therapy
- Fibrosis involving either the foveal center or measuring more than 25% of the total lesion area, and/or juxtafoveal or sub-foveal geographic atrophy
- Hemorrhage measuring more than 50% of total lesion area
- Clinically significant ocular disorders (other than nAMD)

If you would like to refer (with their permission) any potential participants who might be eligible for the ShORe Study, or if you have any questions, please feel free to contact me using the details below.

Sincerely,

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