FOR IMMEDIATE RELEASE

Allegro Ophthalmics Receives FDA Agreement Under Special Protocol Assessment (SPA) for Phase 2b/3 Clinical Trial of Risuteganib for the Treatment of Intermediate Dry AMD

- *Intermediate Dry AMD Treatment Is a Significant Unmet Need*
- *Mitochondrial Stabilizing Candidate Risuteganib Has Shown Best Corrected Visual Acuity Gains in Dry AMD Patient Population*

SAN JUAN CAPISTRANO, CA — April 12, 2023 — Allegro Ophthalmics, LLC, a privately held biopharmaceutical company focused on the development of novel mitochondrial stabilizers for the treatment of ocular diseases, today announced that the Company has received agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the design of its Phase 2b/3 clinical trial of risuteganib (Luminate®) for the treatment of intermediate, non-exudative age-related macular degeneration (dry AMD). Finalization of this assessment indicates that the FDA agrees that critical elements of the overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) are adequate and acceptable for a study intended to support a future marketing application.

"We are excited that the overall protocol design of our Phase 2b/3 dry AMD clinical trial was finalized by the FDA," said Vicken Karageozian, M.D., President and CEO of Allegro Ophthalmics, LLC. "The agreement by the FDA of the SPA provides a clear regulatory path for our first-in-class drug, risuteganib, for the treatment of intermediate dry AMD for an unmet medical need. This is important because dry AMD leads to irreversible, and in many cases catastrophic, vision loss. A therapy to treat this disease is greatly needed."

The Phase 2b/3 study design is based on Allegro's successfully completed U.S. Phase 2a study, in which the primary endpoint was the proportion of subjects with a gain of ≥ 8 letters of vision with two risuteganib injections versus one sham treatment. The Phase 2a trial was a prospective, randomized, double masked, placebo-controlled, multi-center U.S. study that evaluated the safety and efficacy of risuteganib in patients with intermediate dry AMD. The primary endpoint was met, with 48 percent of patients in the risuteganib arm at week 28 and 7 percent of patients in the sham group at week 12 gaining ≥ 8 letters from baseline (p=0.013). Risuteganib was found to be safe, with no reported drug related serious adverse events (SAEs).

Additional findings that support the visual acuity improvement included improvements in retinal sensitivity (microperimetry) and color vision (Lanthony color test).

The Phase 2b/3a study will evaluate efficacy at 52 weeks and safety through 96 weeks. Patients will receive 5 intravitreal injections (IVTs) 12 weeks apart with continued IVT treatment during the follow-up safety portion of the study. The primary endpoint of the study is the improvement in best corrected visual acuity (BCVA) at 52 weeks in the active risuteganib group vs the sham control group. This study design also includes threshold OCT screening, such as minimum ellipsoid zone and photoreceptor layer thickness, that strongly predicts BCVA response to treatment, thus helping clinicians predict outcomes and select the patients most likely to benefit from treatment.

About Allegro Ophthalmics, LLC

Allegro Ophthalmics, LLC is a privately held biopharmaceutical company focused on the development of novel oxidative stress stabilizers for the treatment of ocular diseases. Pre-clinical data suggest that risuteganib (Luminate®), Allegro's lead investigational compound in retina, may simultaneously act on the angiogenic, inflammatory and mitochondrial metabolic pathways implicated in diseases, such as dry AMD. A U.S. Phase 2a study with risuteganib in less advanced dry AMD met its primary endpoint of vision recovery. Expanding its oxidative stress-stabilizing portfolio, Allegro developed ALG-1007 for topical use in dry eye disease. ALG-1007 demonstrated promising results in two ex-U.S. studies in humans. For more information, visit www.allegroeye.com.

Risuteganib (Luminate®) and ALG-1007 are investigational drugs and are not approved for commercial sale.

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