FOR IMMEDIATE RELEASE

Allegro Ophthalmics Announces Positive Topline Vision Results of Phase 2 Study Evaluating Risuteganib in Patients with Intermediate Dry Age-Related Macular Degeneration

-- U.S. Phase 2 Trial Met Primary Endpoint with Statistical Significance
-- 48% of Patients in the Risuteganib Arm Gained ≥ 8 Letters of Vision from Baseline

SAN JUAN CAPISTRANO, CA — June 4, 2019 — Allegro Ophthalmics, LLC, a privately held biopharmaceutical company focused on the development of novel anti-integrin therapies for the treatment of ocular diseases, today announced positive topline results of its U.S. Phase 2 study of risuteganib (Luminate®) for the treatment of intermediate nonexudative age-related macular degeneration (dry AMD). The clinical trial met its primary endpoint with 48 percent of patients in the risuteganib arm gaining ≥ 8 letters of vision at week 28 compared to baseline.

The primary endpoint of the Phase 2 study was the proportion of subjects with a ≥ 8 letters of vision gain with two risuteganib injections versus one sham treatment. The 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. At baseline, 40 patients were randomized to receive either intravitreal 1.0mg risuteganib or sham injection. At week 16, patients in the risuteganib arm received a second dose of 1.0mg risuteganib, and patients in the sham arm crossed over and received a single dose of 1.0mg risuteganib. The primary endpoint was the percentage of the population with ≥ 8 letters ETDRS BCVA gain from baseline to week 28 in the 1.0mg risuteganib arm versus from baseline to week 12 in the sham arm. The primary endpoint was prespecified as ≥ 8 letters to account for the variability in visual acuity measurements among 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). Secondary outcomes, including microperimetry, color vision, and low luminance visual acuity, are currently being evaluated; results of which will be released in the upcoming weeks.

“Allegro’s anti-integrin portfolio continues to show great progress,” said Vicken Karageozian, M.D., President and CEO of Allegro Ophthalmics, LLC. “This progress is supported by recent findings released last month establishing that our ALG-1007 drug candidate for dry eye disease performed well in an ex-U.S. proof-of-concept clinical trial and now by these positive topline U.S. Phase 2 results of risuteganib for intermediate dry AMD. It is very encouraging to see such robust visual acuity gains in patients with dry AMD, a sight-threatening disease for which there is currently no available treatment. It is also exciting to see that these initial clinical findings in dry AMD confirm our extensive preclinical findings and earlier clinical studies that suggested risuteganib could restore visual function.”

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"I've always believed in the potential of integrin inhibition as an alternative target pathway for the treatment of retinal diseases. This Phase 2 data is very promising and suggests what we have always hoped to see: a potential therapy for intermediate dry, nonexudative AMD," said Peter K. Kaiser, M.D., Professor of Ophthalmology at the Cleveland Clinic Lerner College of Medicine and staff surgeon in the Vitreoretinal Department at the Cole Eye Institute, Cleveland Clinic. "If we could add a treatment to our armamentarium that can improve vision in this population of patients that currently is untreatable, this would be significant. I am hopeful for the future of this drug candidate based on the consistency of the data that I have seen across different endpoints."

The full study results, including primary and secondary outcomes, will be presented by Dr. Kaiser at the American Society of Retina Specialists (ASRS) Annual Meeting 2019 in Chicago, IL on Saturday, July 27th.

About Allegro Ophthalmics, LLC
Allegro Ophthalmics, LLC is a privately held biopharmaceutical company focused on the development of novel anti-integrin therapies for the treatment of ocular diseases. Allegro's lead investigational drug risuteganib (Luminate®) successfully completed two Phase 2 diabetic macular edema studies and also has successfully completed a U.S. Phase 2 intermediate dry AMD study. Expanding its anti-integrin portfolio, Allegro has developed ALG-1007, an anti-integrin drug candidate for topical use in dry eye disease. ALG-1007 has successfully completed an ex-U.S. proof-of-concept study in humans, and is currently being evaluated in a larger ex-U.S. Phase 2 study. For more information, visit www.allegroeye.com.

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

Luminate® is a registered trademark of Allegro Ophthalmics, LLC.

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