FOR IMMEDIATE RELEASE

Allegro Ophthalmics Announces Positive Results of Ex-U.S. Proof-of-Concept Trial with Integrin Inhibitor ALG-1007 for Dry Eye Disease

Results of the Trial Suggest that ALG-1007 is Well-Tolerated and Demonstrates a Dose Response with Improvement as Early as Two Weeks

SAN JUAN CAPISTRANO, CA — May 14, 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 results of an ex-U.S. proof-of-concept clinical trial of the new investigational ALG-1007 topical drop drug candidate in patients with dry eye disease (DED). The results were presented by Eric D. Donnenfeld, M.D., last week at the 2019 American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Administrators (ASCRS•ASOA) Annual Meeting in San Diego, CA.[1]

The ex-U.S. proof-of-concept clinical trial concluded that ALG-1007 demonstrated a dose response, indicating that the active pharmaceutical ingredient (API) in ALG-1007 is effective in improving the signs and symptoms of DED with improvement as early as two weeks. At the highest dose concentration (0.6%), ALG-1007 demonstrated statistically significant efficacy in nearly all assessments and a more rapid onset of action compared to the lowest dose (0.125%). ALG-1007 was well-tolerated with no drug-related adverse events, even at the highest dose, and there was no reported blurring of vision or ocular irritation, even at the time of application.

“Allegro is excited to share our ex-U.S. proof-of-concept data of ALG-1007 for dry eye disease,” said Vicken Karageozian, M.D., President and CEO of Allegro Ophthalmics. “These early results suggest that ALG-1007 improves the signs and symptoms of dry eye, a disease that affects millions of people globally, with symptoms that include scratchy, stinging or burning sensations, and pain or redness in the eye. This frequently blurs vision, reading ability, and produces light sensitivity in many patients. Allegro has initiated a second and larger double-masked, vehicle-controlled ex-U.S. Phase 2 clinical trial, results of which are anticipated in the second half of 2019.”

“This early ex-U.S. proof-of-concept data looks promising, especially at the higher 0.6% ALG-1007 dose. My fellow Allegro Cornea SAB members* and I were particularly impressed by how well-tolerated the drug seems to be,” said Dr. Donnenfeld, founding partner of Ophthalmic Consultants of Long Island and Ophthalmic Consultants of Connecticut. “Dry eye is a multifactorial disease and there remain unmet needs for a very large patient population. It will be interesting to see the outcomes of the second, larger ex-U.S. study, which is exploring the drug’s efficacy and safety in even higher concentrations.”

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The completed prospective, open-label ex-U.S. proof-of-concept clinical trial enrolled 40 eyes of 21 patients diagnosed with DED for at least six months. Patients were assigned to one of four treatment doses (n=10, each group): 0.125%, 0.25%, 0.4% and 0.6% of ALG-1007 in a lubricating ophthalmic topical solution. Topical treatment was administered as one drop two times per day, and subjects were followed at multiple timepoints for 12 weeks. Outcome measures were tear break-up time (TBUT), SICCA total ocular staining score, corneal and nasal conjunctival staining score, and reported symptoms using the visual analog scale (VAS) symptom index.

*The Allegro Cornea Scientific Advisory Board (SAB) includes Drs. Richard L. Lindstrom, Edward J. Holland and Eric D. Donnenfeld.

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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 (DME) studies and is currently being evaluated in a U.S. Phase 2 intermediate dry age-related macular degeneration (intermediate dry AMD) study. Expanding its anti-integrin portfolio, Allegro has developed ALG-1007, an anti-integrin drug candidate for topical use in DED. 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.

Source:
1. Donnenfeld E, Holland E, Lindstrom R, Vardanyan A, Adamyan T, Karageozian L, Aubel J, Sarayba M. *A Pilot Study to Evaluate the Safety and Exploratory Efficacy of ALG-1007 Topical Ophthalmic Solution for the Treatment of Dry Eye Disease*. 2019 ASCRS•ASOA.

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