FOR IMMEDIATE RELEASE

Allegro Ophthalmics Announces Positive Results of Vehicle-controlled Ex-U.S. Phase 2 Trial of ALG-1007 for the Treatment of Dry Eye Disease

Allegro also announces FDA acceptance of IND for ALG-1007 for dry eye disease, clearing path to initiate Phase 2b/3 U.S. study

SAN JUAN CAPISTRANO, CA — July 24, 2021 — Allegro Ophthalmics, LLC, a privately held biopharmaceutical company focused on the development of novel oxidative stress stabilizers for the treatment of ocular diseases, today announced that all primary and secondary endpoints of an ex-U.S. vehicle-controlled study of ALG-1007 topical eye drop in patients with dry eye disease (DED) were met. The results were presented by Eric D. Donnenfeld, M.D., at the 2021 American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Administrators (ASCRS ASOA) Annual Meeting in Las Vegas.[1]

The study authors determined ALG-1007, a fixed combination of 0.6% risuteganib and 0.125% sodium hyaluronate in a vehicle solution, demonstrated the highest efficacy among four study arms ($p<.001$) comprising various combinations of the solution components. No adverse events, ocular irritation, or prolonged blurring of vision were reported in the study. Compared with patients in the control arms, patients who received ALG-1007 experienced statistically significant better results in tear break-up time, inferior corneal staining, and scores on the dry eye management scale and visual analog scales. Statistical significance versus the control was seen as early as 2 weeks.

The company also announced that the U.S. Food and Drug Administration (FDA) accepted the filing of an Investigational New Drug (IND) application for ALG-1007, paving the way for Phase 2b clinical development in the U.S.

“Allegro is happy to share the results of our second ex-U.S. clinical trial, which continue to suggest that ALG-1007 improves the signs and symptoms of dry eye,” said Vicken Karageozian, M.D., President and CEO of Allegro Ophthalmics. “These results support the development of a U.S.-based phase 2b/3 study. These data, coupled with the FDA’s acceptance of Allegro’s IND application, will allow investigators to collect more data to elucidate our understanding of how ALG-1007 may provide relief to patients with dry eye, a disease that adversely affects millions of people worldwide.”

“I’m very encouraged by the results of this trial, which demonstrated that ALG-1007 had the most robust improvement in signs and symptoms of dry eye compared to the comparator arms,” said Dr. Donnenfeld, founding partner of Ophthalmic Consultants of Long Island and Clinical Professor of Ophthalmology at NYU. “The components in ALG-1007 appear to have synergistic effects. It should be emphasized that no adverse events, ocular irritation, or prolonged blurred vision were reported in the study—an impressive finding.”

The prospective, randomized, double-masked, vehicle-controlled study was conducted in Armenia. Researchers randomly assigned patients to one of four arms (64 eyes total; 16 eyes per arm): vehicle; vehicle and 0.125% sodium hyaluronate; vehicle and 0.6% risuteganib; and ALG-1007, which contains vehicle, 0.125% sodium hyaluronate, and 0.6% risuteganib. Patients struggling with dry eye signs and symptoms for at least 6 months received 1 drop twice daily for 12 weeks, at which point data were collected and analyzed. Exclusion criteria included history of ocular herpetic keratitis, LASIK surgery, or use of glaucoma medication; any ocular surgery in the past 6 months; and current use of DED therapy.

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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.

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

Source:

1. Donnenfeld E, Holland E, Lindstrom R, et al. *Prospective, Randomized, Double-Masked, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topical Risuteganib (ALG-1007) in the Treatment of Dry Eye Disease*. 2021 ASCRS•ASOA.

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MEDIA CONTACT:
Michele Gray
Gray Communications, LLC
(917) 449-9250
michele@mgraycommunications.com