



NEWS ALERT

Allegro Ophthalmics Licensee AffaMed Therapeutics Receives Phase 3 CTA Approval in China for Risuteganib for the Treatment of Intermediate Dry AMD

SAN JUAN CAPISTRANO, CA — September 25, 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 its licensee, AffaMed Therapeutics, has received Clinical Trial Application (CTA) approval from China's National Medical Products Administration to investigate the safety and efficacy of Risuteganib (Luminate®), a first-in-class, new mechanism of action ophthalmic intravitreal injectable product candidate for the treatment of intermediate dry age-related macular degeneration (AMD). Under the CTA approval, Risuteganib is expected to become the first product in China to enter Phase 3 development for the treatment of dry AMD.

Allegro has a Special Protocol Agreement (SPA) in place with the U.S. Food and Drug Administration (FDA) and also received scientific advice from the European Medicines Agency (EMA) to conduct a Phase 3 dry AMD clinical trial to demonstrate improvement in vision in patients with intermediate dry AMD.

“We congratulate Affamed Therapeutics for achieving this regulatory milestone. This sets the stage for multi-region approval of Risuteganib and availability to patients in need,” said Vicken Karageozian, M.D., President and CEO of Allegro Ophthalmics, LLC.

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.

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