



FOR IMMEDIATE RELEASE

Alkeus Pharmaceuticals Announces Gildeuretinol Data Will Be Presented During the 13th International FLORetina ICOOR Congress December 4–7 in Florence, Italy

CAMBRIDGE, Mass., December 04, 2025 – Alkeus Pharmaceuticals, Inc., a biopharmaceutical company dedicated to preserving the sight of individuals impacted by retinal diseases, today announced that data from its clinical studies of investigational oral gildeuretinol for the treatment of Stargardt disease and Geographic Atrophy (GA) will be presented at the 13th International FLORetina ICOOR Congress being held December 4-7 at the Fortezza de Basso in Florence, Italy.

Oral Presentations:

Gildeuretinol in Stargardt Disease: Results from the TEASE-2 Program

Session: Retina Futura: Spotlight on Emerging Therapies for IRDs

Date: December 6, 2025

Time: 11:02 a.m. – 11:06 a.m. CET

Location: Santa Croce Room, Fortezza de Basso

Presenter: Philip Ferrone, M.D., Vitreoretinal Consultants of New York

Safety and Efficacy of Oral Gildeuretinol in Geographic Atrophy: Results of SAGA, a Phase 2/3 Clinical Study

Session: Retina Futura: Highlights in GA: Current clinical updates and emerging therapies

Date: December 6, 2025

Time: 4:25 p.m. – 4:29 p.m. CET

Location: San Giovanni Room, Fortezza de Basso

Presenter: Dilsher Dhoot, M.D., FASRS, California Retina Consultants

About Alkeus Pharmaceuticals

Alkeus Pharmaceuticals, Inc. is a private biopharmaceutical company dedicated to preserving the sight of individuals impacted by retinal diseases. Based in Cambridge, Mass., Alkeus is backed by institutional investors led by Bain Capital Life Sciences. Alkeus is developing therapies for serious diseases of the eye with high unmet need. Alkeus' breakthrough-designated lead candidate, gildeuretinol acetate (ALK-001), currently is being evaluated in clinical trials for the treatment of Stargardt disease.

About Gildeuretinol Acetate (ALK-001)

Oral gildeuretinol acetate (ALK-001) is a new molecular entity designed to reduce the dimerization of vitamin A without modulating the visual cycle. Gildeuretinol is being evaluated in clinical trials for the treatment of Stargardt disease and has been studied for geographic atrophy secondary to age-related macular degeneration. Gildeuretinol has received Breakthrough Therapy, Rare Pediatric Disease, Fast Track and Orphan Drug designations for Stargardt

disease from the U.S. Food and Drug Administration (FDA). The European Medicines Agency (EMA) has designated giledeuretinol as an orphan medicinal product for the treatment of non-syndromic inherited retinal dystrophies due to defects in the *ABCA4* gene, which includes Stargardt disease.

About the TEASE Program

The Tolerability and Effects of ALK-001 on Stargardt disease (TEASE) studies consist of four independent clinical studies of oral giledeuretinol (ALK-001) in Stargardt disease, denoted as TEASE-1, TEASE-2, TEASE-3 and TEASE-4. The TEASE-1 study was a randomized, double-masked, placebo-controlled trial in patients with advanced Stargardt disease. The TEASE-2 trial was a randomized, double-masked, placebo-controlled trial in patients with moderate Stargardt disease. TEASE-1 and TEASE-2 have been completed. TEASE-3 (NCT02402660), an ongoing clinical trial in early-stage Stargardt disease, is an open-label study of giledeuretinol in genetically confirmed patients with early signs of disease visible on retinal imaging, but who have not begun experiencing symptoms of vision loss. TEASE-4 (NCT04239625) is an open-label extension study.

About the SAGA study

The Study of ALK-001 in GA secondary to age-related macular degeneration (SAGA) (NCT03845582) was a 24-month, double-masked, randomized, placebo-controlled trial to investigate safety, pharmacokinetics, tolerability and efficacy in 198 patients with geographic atrophy secondary to age-related macular degeneration and is complete.

For further information, please contact:

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