



FOR IMMEDIATE RELEASE

Alkeus Pharmaceuticals Announces Presentation of Gildeuretinol Data at the American Academy of Ophthalmology (AAO) 2025 Annual Meeting, October 18-21 in Orlando

Results from the study of oral gildeuretinol in moderate Stargardt disease to be presented as late-breaker during Retina Subspecialty Day

CAMBRIDGE, Mass., October 09, 2025 – Alkeus Pharmaceuticals, Inc., a biopharmaceutical company dedicated to preserving the sight of individuals impacted by retinal diseases, today announced that results from its clinical study of investigational oral gildeuretinol for the treatment of moderate Stargardt disease (TEASE-2) will be presented at the 129th annual meeting of the American Academy of Ophthalmology (AAO) being held in Orlando, October 18-21, 2025.

Oral presentation

Safety and Efficacy of Oral Gildeuretinol in Participants with Intermediate-Stage Stargardt Disease

- **Date/Time:** Retina Subspecialty Day 2025, October 18, 8:23 a.m. – 8:30 a.m. EDT
- **Session:** Section XI: Late Breaking Developments, Part II
- **Location:** Orange County Convention Center, Orlando
- **Presenter:** Philip J. Ferrone, M.D., Vitreoretinal Consultants of New York

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, with the purpose to preserve the sight of individuals impacted by retinal diseases. 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.

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