FOR IMMEDIATE RELEASE

Alkeus Announces Publication in *JAMA Ophthalmology* of Efficacy and Safety Results from the TEASE-1 Study of Gildeuretinol in Stargardt Disease

- Daily treatment with oral gildeuretinol met the primary endpoint and resulted in a statistically significant reduction in the growth rate of retinal atrophic lesions compared to untreated group.

- Gildeuretinol was well tolerated with no patient-reported events of dark adaptation delays or night blindness.

- The publication provides the first peer-reviewed report of efficacy and safety results from a randomized, double-masked, placebo-controlled study in Stargardt disease.

CAMBRIDGE, Mass., September 3, 2026 – Alkeus Pharmaceuticals, Inc., a biopharmaceutical company dedicated to preserving the sight of individuals impacted by retinal diseases, today announced the publication in the *Journal of the American Medical Association (JAMA) Ophthalmology* of the efficacy and safety results from TEASE-1, a randomized, double-masked, placebo-controlled study of investigational oral gildeuretinol as a potential treatment for Stargardt disease. The peer-reviewed publication reports results from the study's primary efficacy endpoint, two prespecified sensitivity analyses, and safety results over 24 months.

The manuscript titled "Safety and Effects of Gildeuretinol Acetate on Retinal Atrophic Lesions in Stargardt Disease," reported that TEASE-1 met its primary endpoint. Daily oral gildeuretinol treatment resulted in a statistically significant and clinically meaningful 21.6% reduction in the transformed (square root) growth rate of retinal atrophic lesions in individuals with Stargardt disease compared to the untreated group (0.182 mm/year versus 0.232 mm/year, a mean difference of -0.050 mm/year [95% CI, -0.072 to -0.027], $p<0.001$). A prespecified sensitivity analysis using untransformed (non-square root) lesion area further supported the primary endpoint results showing a 29.3% reduction in lesion growth rate with gildeuretinol compared to the untreated group (0.867 mm^2/year versus 1.230 mm^2/year, a mean difference of -0.363 mm^2/year [95% CI, -0.498 to -0.228], $p<0.001$).

"As a retina specialist, I have seen first-hand the devastating impact that Stargardt disease has on patients and their families, highlighting the significant unmet need for a safe and effective treatment option," said Carlos Quezada-Ruiz, M.D., F.A.S.R.S., Chief Medical Officer of Alkeus Pharmaceuticals. "As retinal atrophic lesions expand, patients progressively and irreversibly lose the central vision they rely on every day. TEASE-1 showed that gildeuretinol significantly reduced that lesion growth, an important finding because slowing this damage has the potential to help patients preserve their vision longer. Together with a tolerability profile suited to a possible long-term therapy and experience in more than 400 treated patients, these results give us greater confidence in NORTHSTAR and the potential of gildeuretinol."

The TEASE-1 study was a randomized, double-masked, placebo-controlled trial of gildereutinol in 50 patients with Stargardt disease who had retinal atrophy at baseline. Stargardt disease is an inherited rare, progressive condition that leads to irreversible central vision loss. Participants ranged in age from 18-60 years old. The study measured the growth rate of retinal atrophic lesions in patients treated with daily oral gildeuretinol compared to untreated patients (placebo and natural history), as well as safety assessments over 24 months.

The positive treatment effect was supported by two pre-specified sensitivity analyses and remained consistent across multiple prespecified subgroups. The majority of adverse events in TEASE-1 were mild or moderate with no reports of delayed dark adaptation or night blindness. Gildeuretinol was well tolerated and demonstrated a consistent safety profile across the TEASE program to date.

“Reducing the growth rate of retinal atrophic lesions in individuals living with Stargardt disease is critically important to this patient population, which currently has no approved treatment option to slow the irreversible loss of visual function,” said Christine N. Kay, M.D., vitreoretinal surgeon and Director of Research at Vitreoretinal Associates, Gainesville, Fla., and lead author. “The results of this study are extremely promising. Oral gildeuretinol demonstrated a clinically significant effect on the rate of atrophic lesion growth, demonstrating the potential to slow the progression of this relentless disease. Importantly, gildeuretinol was well-tolerated, supporting its potential as a long-term treatment approach.”

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 gildeuretinol 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. The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted Orphan Drug Designation for gildeuretinol for the treatment of 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 gildeuretinol (ALK-001) in Stargardt disease, denoted as TEASE-1, TEASE-2, TEASE-3 and TEASE-4. The TEASE-1 (NCT02402660) study was a randomized, double-masked, placebo-controlled trial in patients with retinal atrophy at baseline in Stargardt disease. The TEASE-2 (NCT02402660) trial was a randomized, double-masked, placebo-controlled trial in patients with decreased retinal sensitivity in Stargardt disease. TEASE-3 (NCT02402660) is an open-label study of gildeuretinol in genetically confirmed patients with early signs of Stargardt 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 NORTHSTAR Study

Alkeus is actively enrolling its global Phase 3 NORTHSTAR Study (NCT07419334) of gildeuretinol as a potential treatment for patients with Stargardt disease. NORTHSTAR is a randomized, placebo-controlled, double-masked 24-month trial designed to evaluate the efficacy and safety of investigational gildeuretinol in people living with Stargardt disease. The primary endpoint is the rate of growth of atrophic lesions from months 6 to 24 comparing gildeuretinol to placebo. The key secondary endpoint is the preservation of visual acuity as measured by low luminance visual acuity (LLVA). Alkeus aims to enroll approximately 230 participants globally in the study between the ages of 8 and 45, building on previously observed findings across more than 400 patients treated with gildeuretinol to date.

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. Tarsus Pharmaceuticals, Inc. (Nasdaq: TARS) announced on August 6, 2026, that it has entered into a definitive agreement to acquire Alkeus. The pending transaction is expected to close in 2026, subject to the satisfaction of customary closing conditions. There can be no assurances that the pending acquisition of Alkeus will be consummated on the terms and in the timing described herein or at all. 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 a Phase 3 clinical trial for the treatment of Stargardt disease.

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