FOR IMMEDIATE RELEASE

Alkeus Pharmaceuticals Announces Two Presentations of Oral Gildeuretinol Data During the 48th Annual Meeting of the Macula Society Being Held February 12-15, 2025

CAMBRIDGE, Mass., February 11, 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 studies of investigational oral gildeuretinol for the treatment of Stargardt disease (TEASE) and geographic atrophy secondary to age-related macular degeneration (SAGA) will be presented at the 48th Annual Meeting of the Macula Society being held February 12-15 in Charlotte Harbor, Fla.

Oral Presentations:

- **Oral Gildeuretinol Slows Progression of Stargardt Disease: Safety and Efficacy Results from The TEASE Program**
  Session: INHERITED RETINAL DYSTROPHY I: TRIALS
  Date: February 13, 2025
  Time: 7:35 a.m. – 7:40 a.m. EST
  Location: Great Egret Ballroom
  Presenter: Philip Ferrone, M.D., Vitreoretinal Consultants of New York

- **Oral Gildeuretinol in Geographic Atrophy Secondary to AMD: Safety and Efficacy from SAGA, a 2-Year, Randomized, Double-Masked, Placebo-Controlled Study**
  Session: NON-NV AMD I: TRIALS
  Date: February 13, 2025
  Time: 8:15 a.m. – 8:20 a.m. EST
  Location: Great Egret Ballroom
  Presenter: Ivan Jose Suner, M.D., M.B.A., Retina Associates of Florida

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 study was a randomized, double-masked, placebo-controlled trial in 50 patients with Stargardt disease. Gildeuretinol met its prespecified primary efficacy endpoint showing a 21.6% reduction in the growth rate of retinal atrophic lesions area (square root) ($p<0.001$), and a 29.5% reduction for untransformed areas of retinal atrophic lesions against untreated patients. Gildeuretinol was well-tolerated. The TEASE-2 trial is an ongoing, fully enrolled, randomized, double-masked, placebo-controlled trial in 80 patients with moderate Stargardt disease, expected to read out topline data in 2025. TEASE-3, the first clinical trial in early-stage Stargardt disease, is an open-label study of gildeuretinol 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 is an open-label extension study.

About the SAGA Study

The Study of ALK-001 in GA (SAGA) was a 24-month, double-masked, randomized, placebo-controlled trial to investigate safety, pharmacokinetics, tolerability and efficacy in patients with GA secondary to AMD. The study enrolled 198 patients. The primary efficacy endpoint was the growth rate of GA lesions from baseline to 24 months as assessed by Fundus Autofluorescence (FAF). The first key secondary endpoint was the change in low luminance visual acuity (LLVA) from baseline to 24 months.

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. In preclinical studies, gildeuretinol decreased vitamin A dimerization down to the normal rate and prevented retinal degeneration and loss of visual function in animals with Stargardt disease. A randomized, placebo-controlled, double-masked clinical trial of gildeuretinol in late-stage Stargardt patients (TEASE-1) showed clinically and statistically significant slowing of the growth of retinal lesions over two years of treatment. Additional clinical trials of gildeuretinol in Stargardt disease are ongoing. 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. A study (SAGA) of gildeuretinol in 198 patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD) demonstrated a meaningful trend in the reduction of lesion growth rate and demonstrated a functional benefit in low luminance visual acuity (LLVA). In studies, gildeuretinol demonstrated a favorable safety and tolerability profile.

About Alkeus Pharmaceuticals

Alkeus Pharmaceuticals, Inc. is a private biopharmaceutical company with headquarters in Cambridge, Mass., backed by institutional investors led by Bain Capital Life Sciences. Founded in 2010, 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), is a new chemical entity currently being evaluated in clinical trials for the treatment of Stargardt disease and for geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
For further information, please contact:

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