Alumis Announces Late-Breaker Psoriasis Presentation of 52-week Phase 2 OLE Data for ESK-001 at 2025 American Academy of Dermatology Annual Meeting and Accelerated Topline Phase 3 Data Readout

February 28, 2025

– Late-breaking oral presentation to highlight 52-week data of ESK-001 in a Phase 2 open-label extension (OLE) study in adults with moderate-to-severe plaque psoriasis –

– Additional Phase 2 e-poster presentations to describe patient-reported outcomes, disease biomarker activity and pharmacokinetic data of ESK-001 in psoriasis patients –

– Phase 3 ONWARD program topline data now expected in Q1 2026 –

SOUTH SAN FRANCISCO, Calif., Feb. 28, 2025 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS) (“Alumis” or the “Company”), a clinical stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases, today announced the Company will give four data presentations from its Phase 2 OLE study evaluating ESK-001, a next-generation oral tyrosine kinase 2 (TYK2) inhibitor, in moderate-to-severe psoriasis (PsO) patients at the 2025 American Academy of Dermatology (AAD) annual meeting from March 7 to 11, 2025, in Orlando, Florida. The Company also announced that it now expects to report topline data from its pivotal Phase 3 ONWARD clinical program of ESK-001 for the treatment of moderate-to-severe PsO in the first quarter of 2026.

“We are pleased to have these Phase 2 OLE data for ESK-001 selected for late-breaking oral and e-poster presentations at the annual AAD meeting and the opportunity to share these important results with the dermatology community,” said Martin Babler, President and Chief Executive Officer of Alumis. "In addition, as a result of our program execution and the strong interest from patients and clinical investigators, we have accelerated our expected topline Phase 3 clinical data milestone to the first quarter of 2026.”

Details regarding the presentations are as follows:

Late-Breaking Oral Presentation
Title: Efficacy and Safety of ESK-001, a Highly Selective Oral TYK2 inhibitor, in Moderate-to-Severe Plaque Psoriasis: Long-term Phase 2 Results
Location: Chapin Theater - Level II
Date and Time: March 8, 2025, at 11:00 am EST

E-Poster Presentations

Title: Patient-Reported Outcomes in the Phase 2 Studies of ESK-001, an Oral Allosteric TYK2 Inhibitor, in Adults with Moderate-to-Severe Plaque Psoriasis
Poster number: 64301

Title: Pharmacokinetics, Safety, and Tolerability of ESK-001, an Allosteric TYK2 Inhibitor for Plaque Psoriasis: Evaluation in Asian Populations Compared to Caucasians
Poster number: 62945

Title: ESK-001, an Allosteric TYK2 Inhibitor, Modulates Disease and TYK2-related Pathway Transcriptomic and Proteomic Biomarkers in Psoriasis STRIDE Trial Patients
Poster number: 62905

The presentations will be made available under the Publications section of the Alumis website on March 8, 2025.

About ESK-001
Alumis' lead clinical candidate, ESK-001, is a highly selective, next-generation oral TYK2 inhibitor that is designed to correct immune dysregulation across a spectrum of diseases driven by proinflammatory mediators, including IL-23, IL-17, and type 1 interferon. ESK-001's selective targeting is designed to deliver maximal target inhibition while minimizing off-target binding and effects.

ESK-001 is currently being evaluated in the Phase 3 ONWARD clinical program, which consists of two parallel, global Phase 3, multi-center, randomized, double-blind placebo-controlled 24-week clinical trials, ONWARD1 and ONWARD2, designed to evaluate the efficacy and safety of ESK-001 in adult patients with moderate-to-severe plaque psoriasis. Each trial will enroll approximately 840 patients randomized 2:1:1 to receive either ESK-001 40 mg twice-daily, placebo or apremilast. The co-primary efficacy endpoints will be the proportion of patients with moderate-to-severe plaque psoriasis achieving a 75% improvement in the Psoriasis Area and Severity Index (PASI 75) and sPGA score 0/1 of ESK-001 compared to placebo at Week 16. Patients completing Week 24 will have the opportunity to participate in a long-term extension (LTE) trial, ONWARD3, that will evaluate durability and maintenance of response and long-term safety.

The Phase 3 clinical program is supported by positive data from the Phase 2 STRIDE clinical trial (NCT05600036) and from the long-term OLE extension (CT05739435), which is currently ongoing. Interim 28-week OLE data presented at the 2024 European Academy of Dermatology & Venereology Congress demonstrated a dose-dependent sustained increase across all PASI scores over time, with the majority of patients reaching PASI 75 at the 40 mg twice daily dose. ESK-001 continued to show a favorable safety profile in the OLE. Treatment emergent adverse event (TEAE) frequency and severity were similar across study arms, with the most common TEAEs being upper respiratory tract infections, nasopharyngitis, headaches, and the majority mild-to-moderate and self-limited.

In parallel with the Phase 3 clinical program, Alumis is developing a once-daily modified release oral formulation of ESK-001 that can replace the current immediate release oral formulation that is dosed twice daily.

ESK-001 is also being evaluated in LUMUS, a Phase 2b clinical trial of ESK-001 for the treatment of patients with systemic lupus erythematosus. In addition, Alumis continues to leverage its precision

data analytics platform to explore ESK-001’s potential application in other autoimmune indications.

About Alumis

Alumis is a clinical stage biopharmaceutical company developing oral therapies using a precision approach to optimize clinical outcomes and significantly improve the lives of patients with immune-mediated diseases. Leveraging its proprietary precision data analytics platform, Alumis is building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Alumis’ most advanced product candidate, ESK-001, is an oral, highly selective, small molecule, allosteric inhibitor of TYK2 that is currently being evaluated for the treatment of patients with moderate-to-severe plaque psoriasis and systemic lupus erythematosus. Alumis is also developing A-005, a clinical-stage, CNS-penetrant, allosteric TYK2 inhibitor for the treatment of neuroinflammatory and neurodegenerative diseases. Beyond TYK2, Alumis’ proprietary precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify its precision approach. Incubated by Foresite Labs and led by a team of industry veterans experienced in small-molecule compound drug development for immune-mediated diseases, Alumis is pioneering a precision approach to drug development to potentially produce the next generation of treatment to address immune dysfunction. For more information, visit https://www.alumis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding Alumis’ future plans and prospects including development and commercialization of its pipeline, Alumis’ expectations with respect to the timing of availability of topline data from its clinical trials, any expectations regarding the safety, efficacy or tolerability of ESK-001 or A-005, the potential of ESK-001 to treat moderate-to-severe plaque psoriasis and systemic lupus erythematosus, and the potential of A-005 to treat neurodegenerative diseases. Any forward-looking statements in this press release are based on Alumis’ current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Readers are cautioned that actual results, levels of activity, safety, efficacy, performance or events and circumstances could differ materially from those expressed or implied in Alumis’ forward-looking statements due to a variety of risks and uncertainties, which include, without limitation, risks and uncertainties related to Alumis’ ability to advance ESK-001 and A-005 and to obtain regulatory approval of and ultimately commercialize Alumis’ clinical candidates, the timing and results of preclinical and clinical trials, Alumis’ ability to fund development activities and achieve development goals, Alumis’ ability to protect its intellectual property and other risks and uncertainties described in Alumis’ filings with the Securities and Exchange Commission (SEC), including any future reports Alumis may file with the SEC from time to time. Alumis explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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