Late-Breaking ESK-001 Phase 2 OLE Data Presented at 2025 AAD Annual Meeting Demonstrate Robust Clinical Responses Over 52-Weeks in Psoriasis

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- *ESK-001 is a highly selective, next-generation oral tyrosine kinase 2 (TYK2) inhibitor currently under development in moderate-to-severe plaque psoriasis and systemic lupus*
- *Phase 2 OLE data of ESK-001 at 40 mg BID demonstrated sustained or increasing clinical responses through week 52 on PASI 90, PASI 100, and sPGA 0*
- *ESK-001 was generally well-tolerated at one year, with no new safety findings*
- *Data further support ESK-001's potential to offer a highly differentiated and best-in-class treatment option for people with moderate-to-severe plaque psoriasis*
- *Phase 3 ONWARD program ongoing with topline data expected in Q1 2026*

SOUTH SAN FRANCISCO, Calif., March 08, 2025 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS), 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 positive 52-week data from the open-label extension (OLE) of its Phase 2 STRIDE clinical trial evaluating ESK-001 in patients with moderate-to-severe plaque psoriasis. The results were presented during a late-breaking session at the 2025 American Academy of Dermatology Association (AAD) Annual Meeting in Orlando, Florida.

These data demonstrated that patients receiving 40 mg twice daily dosing of ESK-001 achieved long-term sustained or increasing clinical responses through Week 52 compared to Week 12 (using modified non-responder imputation, n=80) as measured by PASI 90 (61.3% vs. 52.4%), PASI 100 (38.8% vs. 26.8%), and sPGA 0 (38.8% vs. 32.9%). At Week 52, patients maintained robust clinical improvements in control of itch (NRS≤4, 81.3%) and quality-of-life (DLQI0/1, 61.3%). Treatment with ESK-001 continued to be generally well tolerated at week 52, with safety and tolerability consistent with previously reported Week 16 and Week 28 data and no new safety findings.

"We're excited to see that ESK-001 continues to demonstrate a favorable clinical profile for the potential treatment of moderate-to-severe plaque psoriasis, with the ability to improve clinical outcomes as well as patients' reported symptoms and quality of life," said Dr. Jörn Drappa, Alumis' Chief Medical Officer. "We believe in the potential of ESK-001 to fill a critical gap in psoriasis patient care as an oral therapy that is well tolerated and may provide biologic-like clinical responses."

ESK-001 is a highly selective, next-generation oral tyrosine kinase 2 (TYK2) inhibitor designed to correct immune dysregulation across a spectrum of diseases driven by proinflammatory mediators, including IL-23, IL-17, and type 1 interferon (IFN). Its selective targeting is designed to deliver maximal inhibition while minimizing off-target binding and effects.

“These long-term data further support the highly differentiated profile of ESK-001 and reinforce its potential as a best-in-class TYK2 inhibitor for the oral treatment of moderate-to-severe plaque psoriasis," said Martin Babler, President and Chief Executive Officer of Alumis. "We continue to progress and enroll patients with moderate-to-severe psoriasis in the pivotal Phase 3 ONWARD studies and expect to report topline data in the first quarter of 2026.”

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 (IFN). ESK-001's selective targeting is designed to deliver maximal 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 the long-term OLE extension (CT05739435), which is currently ongoing. Interim 28-week OLE data presented at the 2024 European Academy of Dermatology & Venereology (EADV) 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 being upper respiratory tract infections, nasopharyngitis, and 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 designed to 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 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 immune-mediated conditions.

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 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, the potential for ESK-001 to be a best-in-class oral treatment for moderate-to-severe plaque psoriasis, any expectations regarding the safety, efficacy or tolerability of ESK-001 and the potential of ESK-001 to treat moderate-to-severe plaque psoriasis and systemic lupus erythematosus. 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 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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