Alumis Completes Enrollment of Pivotal Phase 3 ONWARD Clinical Program of Lead Candidate ESK-001, a Highly Selective, Next-Generation Oral TYK2 Inhibitor for the Treatment of Moderate-to-Severe Plaque Psoriasis

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-Topline readout expected in early Q1 2026-

SOUTH SAN FRANCISCO, Calif., May 29, 2025 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS), a late-stage biopharma company developing next-generation targeted therapies for patients with immune-mediated diseases, today announced the completion of patient enrollment in its pivotal Phase 3 ONWARD clinical program of ESK-001 for the treatment of moderate-to-severe plaque psoriasis.

"We are excited to announce the completion of patient enrollment in our pivotal Phase 3 ONWARD clinical program evaluating ESK-001 for moderate-to-severe plaque psoriasis," said Martin Babler, President and Chief Executive Officer of Alumis. "With over 1,700 patients enrolled across the two trials, this milestone reflects the dedication of our patients, investigators, and the Alumis team, whose efforts have made it possible. We remain on track to report topline results in early Q1 2026, bringing us closer to delivering transformative treatment solutions for patients in need."

"As we advance the development of ESK-001, we recognize the ongoing challenges patients with plaque psoriasis face in finding effective and convenient treatment options," said Dr. Jörn Drappa, Alumis' Chief Medical Officer. "Many patients cycle through therapies due to the inconvenience of injectable biologics and the diminishing effectiveness of oral treatments. With its differentiated profile, ESK-001 has the potential to provide a well-tolerated oral TYK2 inhibitor that delivers durable, biologic-like clinical responses, bridging a critical gap in treatment."

The Phase 3 ONWARD clinical program 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. ONWARD 3, an optional long-term extension trial for patients who have completed Week 24, is currently ongoing to assess the durability, maintenance of response, and long-term safety of ESK-001.

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.

The efficacy and safety of ESK-001 in adult patients with moderate-to-severe plaque psoriasis are 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 (NCT06586112) and ONWARD2 (NCT06588738). Over 1,700 patients were enrolled across the two trials and randomized 2:1:1 to receive 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 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 by the long-term open-label extension (CT05739435) which is currently ongoing. 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 late-stage biopharma company developing next-generation targeted therapies with the potential to significantly improve patient health and outcomes across a range of immune-mediated diseases. Leveraging its proprietary data analytics platform and precision approach, Alumis is developing a pipeline of oral tyrosine kinase 2 inhibitors, consisting of ESK-001 for the treatment of systemic immune-mediated disorders, such as moderate-to-severe plaque psoriasis and systemic lupus erythematosus, and A-005 for the treatment of neuroinflammatory and neurodegenerative diseases. In addition, the pipeline includes lonigutamab, a subcutaneously delivered anti–insulin-like growth factor 1 receptor therapy for the treatment of thyroid eye disease, as well as several preclinical programs identified through this precision approach. For more information, visit www.alumis.com or follow us on LinkedIn or X.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of federal securities laws, including 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. All statements, other than statements of historical facts, including without limitation those regarding the timing of Alumis' topline readout in its ONWARD Phase 3 program, the potential for ESK-001 to treat moderate-to-severe plaque psoriasis and systemic lupus erythematosus, any expectations regarding the safety, efficacy or tolerability of ESK-001 and statements regarding Alumis' future plans and prospects including development of its clinical pipeline; and any assumptions underlying any of the foregoing, are forward-looking statements. 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

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