Alumis' Envudeucitinib Delivers Leading Skin Clearance Among Next-Generation Oral Plaque Psoriasis Therapies in Phase 3 Program

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– Both Phase 3 trials met all primary and secondary endpoints with high statistical significance in patients with moderate-to-severe plaque psoriasis –

– Approximately 65% of patients achieved PASI 90 and more than 40% achieved PASI 100 at Week 24, on average –

– Envudeucitinib demonstrated a favorable safety and tolerability profile consistent with the Phase 2 program –

– Alumis plans to submit a New Drug Application to the FDA in the second half of 2026 –

– Conference call and webcast scheduled for 8:00 a.m. ET today –

SOUTH SAN FRANCISCO, Calif., Jan. 06, 2026 (GLOBE NEWSWIRE) -- Alumis Inc. (Nasdaq: ALMS), a late-stage biopharmaceutical company developing next-generation targeted therapies for patients with immune-mediated diseases, today announced positive topline results from its Phase 3 ONWARD1 and ONWARD2 clinical trials of envudeucitinib, a next-generation highly selective oral tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate-to-severe plaque psoriasis.

Envudeucitinib met all primary and secondary endpoints with high statistical significance in ONWARD1 and ONWARD2. In each of these trials, envudeucitinib achieved superior skin clearance compared with placebo ($p < 0.0001$) on the co-primary endpoints of Psoriasis Area and Severity Index (PASI) 75 and static Physician's Global Assessment (sPGA) 0/1 at Week 16. On average across both ONWARD1 and ONWARD2, 74% of patients achieved PASI 75 and 59% of patients achieved sPGA 0/1, with responses deepening over time. In addition, the placebo-adjusted response rates for the co-primary endpoints were consistent between the two trials.

At Week 24, on the higher hurdle skin clearance measures, approximately 65% of patients achieved PASI 90, and more than 40% achieved PASI 100, on average across both trials. Rapid responses were observed, with clear separation from placebo on PASI 90 as early as Week 4. In addition, consistent and clinically meaningful improvements across patient-reported outcomes relating to itch and quality of life were observed. Envudeucitinib also achieved superior skin clearance compared with apremilast in each trial ($p<0.0001$) on all PASI endpoints at Week 24.

"We believe envudeucitinib demonstrates the full promise of TYK2 inhibition," said Dr. Jörn Drappa, Chief Medical Officer of Alumis. "By maximally inhibiting TYK2, envudeucitinib blocks both IL-23 and IL-17 to deliver comprehensive disease control. In Phase 3, this translated into rapid onset of action, high rates of skin clearance, and meaningful symptom improvements that rank among the strongest

reported for an oral therapy. We are deeply grateful to the patients, families, and investigators whose commitment made this milestone possible."

Treatment with envudeucitinib was generally well tolerated through Week 24 in both trials, with a safety profile consistent with Alumis' Phase 2 program, including the long-term extension trial. Treatment-emergent adverse event (TEAE) frequency and severity were similar across trials, with the majority being mild to moderate, transient, and responding to standard therapy, if required. The most common TEAEs were headaches, nasopharyngitis, upper respiratory tract infections, and acne. No new safety signals were observed.

"Patients with moderate-to-severe psoriasis have to choose between oral and biologic therapies," said leading dermatologist and psoriasis expert Dr. Andrew Blauvelt. "And for individuals seeking the best chance for clearance, biologics have long been superior to oral therapies. But now, with these new data on envudeucitinib, we're seeing an exciting possibility of a new oral drug for psoriasis that can deliver high levels of efficacy in a safe manner."

"These pivotal data strengthen our conviction in envudeucitinib's potential to transform the treatment landscape for IL-23/IL-17–driven diseases as well as those driven by Type I interferon," said Martin Babler, Chief Executive Officer of Alumis. "These results reinforce our enthusiasm that envudeucitinib's highly differentiated clinical profile positions it at the forefront of next-generation TYK2 inhibitors in psoriasis, with potential in systemic lupus erythematosus and beyond as a true pipeline-in-a-pill."

Alumis plans to present additional results from ONWARD1 and ONWARD2 at an upcoming medical meeting and to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration in the second half of this year. Topline data from the LUMUS Phase 2b trial of envudeucitinib in systemic lupus erythematosus (SLE) are expected to be announced in the third quarter of 2026.

Conference Call and Webcast Details
The webcast of the Phase 3 ONWARD topline results will begin today at 8:00 a.m. ET. The live webcast can be accessed via this link or on the Events tab on the Investors section of the Company's website. A replay of the webcast will be made available on the Company's website following the call.

About the Phase 3 ONWARD Clinical Program
The Phase 3 ONWARD clinical program includes two parallel global, multi-center, randomized, double-blind, placebo and active-comparator-controlled 24-week trials—ONWARD1 (NCT06586112) and ONWARD2 (NCT06588738)—evaluating the efficacy and safety of envudeucitinib in adults with moderate-to-severe plaque psoriasis. More than 1,700 patients were enrolled and randomized 2:1:1 to receive envudeucitinib 40 mg twice daily, placebo, or apremilast. Co-primary endpoints at Week 16 were the proportion of patients achieving Psoriasis Area and Severity Index (PASI) 75 and static Physician's Global Assessment (sPGA) 0/1 compared with placebo. Patients completing Week 24 were eligible to enter ONWARD3, an ongoing long-term extension study assessing durability, greater maintenance of response, and long-term safety. The ONWARD clinical trials did not have a fasting requirement.

About Envudeucitinib
Envudeucitinib is a next-generation, highly selective, oral allosteric inhibitor of tyrosine kinase 2 (TYK2) designed to correct immune dysregulation across a range of diseases driven by

proinflammatory mediators, including IL-23, IL-17, and Type I interferon. Clinical data indicate its selective targeting delivered sustained, maximal 24-hour inhibition in patients with psoriasis while minimizing off-target binding and effects. Alumis is currently evaluating the long-term efficacy and safety of envudeucitinib in the Phase 3 ONWARD3 clinical program for moderate-to-severe plaque psoriasis. Envudeucitinib is also being evaluated in LUMUS, a potentially pivotal Phase 2b clinical trial in patients with systemic lupus erythematosus, with topline data expected in the third quarter of 2026.

About Plaque Psoriasis

Plaque psoriasis is a chronic, immune-mediated disease driven by dysregulated IL-23 and IL-17 pathways that cause painful, itchy, scaly patches. It affects more than 8 million adults in the U.S. and often involves high-impact areas such as the scalp, face, hands, feet, and nails, significantly disrupting daily life. According to the National Psoriasis Foundation, about one in four patients has moderate-to-severe disease based on quality-of-life impact and body surface area involved. Many remain inadequately controlled on current oral and topical treatments, underscoring the need for more effective, safe, and durable oral options that address the full burden of disease.

About TYK2 in Immune-Mediated Disease

Tyrosine kinase 2 (TYK2) is a key immune-signaling enzyme that regulates pathways across innate and adaptive immunity, including the IL-23/IL-17 axis and Type I interferon signaling that drive many high-burden immune-mediated diseases. Selective TYK2 inhibition has been widely validated as an effective, safe, and well-tolerated therapeutic approach. Genomic analyses conducted by Alumis highlight TYK2's broad therapeutic potential, showing that it contributes to the pathogenesis of roughly 20 immune-driven conditions—including psoriasis, lupus, psoriatic arthritis, rheumatoid arthritis, Crohn's disease, and ulcerative colitis. Additional evidence supports a genetic rationale for TYK2 inhibition in neuroinflammatory and neurodegenerative diseases such as multiple sclerosis, where targeting TYK2 may offer a novel approach to treatment.

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 envudeucitinib 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 Alumis' plans to submit an NDA in the second half of 2026, the potential

for envudeucitinib to transform the treatment landscape for IL-23/IL-17–driven diseases as well as those driven by Type I interferon, the potential for envudeucitinib to meaningfully elevate care for and effectively reduce the full burden of disease for patients with moderate-to-severe plaque psoriasis, the timing of Alumis' topline readout in its LUMUS Phase 2b program 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 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 whether regulatory authorities determine that envudeucitinib in moderate-to-severe plaque psoriasis is sufficiently safe and efficacious and grant regulatory approval; whether regulatory authorities accept for filing Alumis' planned NDA submission; Alumis' ability 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, and Alumis' ability to protect its intellectual property**.** Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Alumis' filings and reports with the Securities and Exchange Commission (SEC) under the heading "Risk Factors" and elsewhere in such filings and reports, 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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