Alumis Announces Topline Results from Envudeucitinib Phase 2b Trial in Systemic Lupus Erythematosus (SLE)

September 1, 2026

– LUMUS trial did not meet its primary and secondary endpoints in the overall trial population –

– Robust responses in the prespecified subgroup of patients with high interferon gene signature (IFNGS-high) support moving forward with Phase 3 development in SLE –

– Pharmacodynamic data substantiate envudeucitinib's potential in interferon-driven immune-mediated diseases –

– Envudeucitinib was generally well tolerated with no new safety signals observed –

– Alumis remains on track to submit an NDA for envudeucitinib in moderate-to-severe plaque psoriasis in 4Q 2026 –

– Conference call and webcast scheduled for September 1 at 8:30 am EDT –

SAN FRANCISCO, Sept. 01, 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 that its Phase 2b LUMUS trial of envudeucitinib for the treatment of moderate-to-severe systemic lupus erythematosus (SLE) did not meet its primary and secondary endpoints in the overall trial population. Notably, key insights from this trial support a clear path forward for regulatory engagement on Phase 3 development.

Robust clinical responses were observed in a prespecified subgroup analysis of patients with high interferon gene signature (IFNGS-high), including on the primary endpoint, British Isles Lupus Assessment Group–based Composite Lupus Assessment (BICLA), and key secondary efficacy endpoints including Cutaneous Lupus Erythematosus Disease Area and Severity Index 50 (CLASI-50), SLE Responder Index 4 (SRI-4), and Lupus Low Disease Activity State (LLDAS). Patients were classified in LUMUS as IFNGS-high or IFNGS-low using a commercially available interferon gene signature assay.

IFNGS-high patients, a well-defined group representing the majority of moderate-to-severe SLE cases, typically respond more favorably to interferon pathway-targeted therapies and show lower placebo response rates. In LUMUS, IFNGS-high patients were unexpectedly under-represented, reducing response rates in the overall trial population.

"We are extremely grateful to the patients, families, and investigators whose participation made the LUMUS study possible," said Dr. Jörn Drappa, Chief Medical Officer of Alumis. "Although envudeucitinib did not meet its primary objective in the overall trial population, the magnitude of

effect observed in the prespecified IFNGS-high subgroup is highly compelling in a disease with no targeted oral therapies currently available. We plan to engage regulators to discuss Phase 3 development for envudeucitinib."

Patient pharmacodynamic data confirmed robust dose-dependent interferon-pathway target engagement, with maximal suppression observed at the highest dose, 40mg twice-daily, further supporting envudeucitinib's inhibition of the intended biological pathway and its potential in interferon-driven immune-mediated diseases. In LUMUS, envudeucitinib was well tolerated and demonstrated a favorable safety profile with no new safety signals.

"The mechanism validated by these data underscores a multi-indication opportunity for envudeucitinib across Type I interferon-driven diseases, including cutaneous lupus erythematosus and Sjögren's disease," said Martin Babler, Chief Executive Officer of Alumis. "We are actively evaluating opportunities to maximize the value of our oral TYK2 portfolio and remain on track to file an NDA for envudeucitinib in moderate-to-severe plaque psoriasis in the fourth quarter of this year."

Conference Call, Presentation and Webcast Details
Alumis will host a webcast for the investment community to review the Phase 2 LUMUS results which will begin at 5:30 am PDT / 8:30 am EDT on Tuesday, September 1, 2026. 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 LUMUS Phase 2b Trial
The global LUMUS Phase 2b trial (NCT05966480) is a randomized, double-blind, placebo-controlled study evaluating multiple doses of envudeucitinib in adults with moderately-to-severely active, autoantibody-positive systemic lupus erythematosus (SLE). The trial enrolled 408 patients who received one of three envudeucitinib doses or placebo for 48 weeks in Part A. The primary endpoint was the assessment of improvements in overall disease activity using the British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) at Week 48. Select secondary endpoints assessed at Week 48 include safety and tolerability, corticosteroid use, and disease activity measured by Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) and SLE Responder Index-4 (SRI-4). After Part A, eligible patients could complete a four-week safety follow-up or participate in LUMUS Part B, a long-term open label extension study.

About Envudeucitinib
Envudeucitinib is a next-generation, highly selective, oral allosteric inhibitor of tyrosine kinase 2 (TYK2) precision-engineered for maximal 24-hour TYK2 inhibition to correct immune dysregulation across a range of diseases driven by IL-23, IL-17, and Type I interferon. It is the only TYK2 inhibitor shown to deliver maximal target inhibition over 24 hours in humans, with clinical data demonstrating sustained TYK2 blockade in patients with psoriasis while minimizing off-target binding and effects. Envudeucitinib has been administered with or without food, with no fasting requirement. Alumis has reported positive results from its Phase 3 ONWARD program of envudeucitinib in moderate-to-severe plaque psoriasis and plans to file an NDA in moderate-to-severe plaque psoriasis in the fourth quarter of 2026.

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, Sjögren's disease, cutaneous lupus erythematosus, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Additional evidence supports a genetic rationale for TYK2 inhibition in neuroinflammatory and neurodegenerative diseases 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, such as Parkinson's disease. In addition, the pipeline includes 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. Forward-looking statements generally may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and similar expressions intended to identify forward-looking statements. All statements contained in this press release other than statements of historical facts are forward-looking statements, including without limitation statements regarding: Alumis' plans to submit an NDA for envudeucitinib in the fourth quarter of 2026; anticipated regulatory interactions in systemic lupus erythematosus, including the potential for prespecified subgroup analyses to inform future Phase 3 development; the therapeutic potential of TYK2 inhibition across immune-mediated diseases and the potential multi-indication opportunity for envudeucitinib in interferon-driven diseases, including cutaneous lupus erythematosus and Sjögren's disease; the development of A-005 for neuroinflammatory and neurodegenerative diseases, including Parkinson's Disease; the advancement of Alumis' clinical pipeline; Alumis' plans to evaluate opportunities to maximize the value of the company's TYK2 portfolio and Alumis' future plans, strategy, prospects and anticipated milestones, as well as the assumptions underlying any of the foregoing. Forward-looking statements are based on Alumis' current expectations, estimates, assumptions and projections as of the date of this press release and are subject to significant risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Readers are cautioned that actual results, timing, safety, efficacy, performance or events and circumstances may differ materially from those expressed or implied in Alumis' forward-looking statements due to a variety of risks and uncertainties including, without limitation, whether regulatory authorities accept for filing Alumis' planned NDA submission as well as determine that envudeucitinib demonstrates an acceptable safety and efficacy profile and grant regulatory approval in moderate-to-severe plaque psoriasis; whether clinical results observed to date, including subgroup analyses, will be replicated in larger or later-stage clinical trials; the potential for envudeucitinib to be developed in additional indications; the timing and results of clinical trials; Alumis' ability to obtain regulatory approval of and ultimately commercialize its product candidates, Alumis' ability to obtain sufficient funding and achieve anticipated development objectives, and

Alumis' ability to obtain, maintain and enforce intellectual property protection for its programs and product candidates. Additional information regarding these and other risks and uncertainties are contained under the heading "Risk Factors" and elsewhere in Alumis' filings with the Securities and Exchange Commission (SEC) , including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and subsequent filings with the SEC. Alumis explicitly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

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