



Alumis Announces New Phase 3 Data Demonstrating Envudeucitinib Rapidly and Durably Improved Psoriasis Burden Across Scalp, Itch, and Quality of Life Measures

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– Results build on ONWARD3 highest complete skin clearance (54% PASI 100) at Week 48, reinforcing envudeucitinib’s potential to become a leading oral therapy for moderate-to-severe plaque psoriasis

– Patients switching from placebo or apremilast achieved rapid responses, comparable to those on continuous treatment at Week 48

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

SOUTH SAN FRANCISCO, Calif., Oct. 09, 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 new envudeucitinib data from the ONWARD Phase 3 clinical program—ONWARD1, ONWARD2, and the long-term extension ONWARD3. The results, presented at the 26th Annual Fall Clinical Dermatology Conference, reinforce the potential of envudeucitinib to become a leading oral therapy for patients with moderate-to-severe plaque psoriasis. Envudeucitinib is an investigational, next-generation oral TYK2 inhibitor precision-engineered for maximal 24-hour target inhibition.

New data across key measures of disease burden build on envudeucitinib’s high-threshold skin clearance across the ONWARD program, including a 54% Psoriasis Area and Severity Index (PASI) 100 response rate at Week 48—the highest publicly reported among existing and investigational oral psoriasis therapies. The data demonstrated early and durable improvements across scalp disease severity (a high-impact, difficult-to-treat area), itch resolution, and quality of life measures.

“For people living with psoriasis, achieving early and sustained relief in difficult-to-treat areas like the scalp and reduction of burdensome symptoms like itch are outcomes that can meaningfully improve quality-of-life,” said Mark Lebwohl, MD, Dean for Clinical Therapeutics at the Icahn School of Medicine at Mount Sinai. “The consistency of these findings across the ONWARD3 program —alongside high-threshold skin clearance and a favorable tolerability profile—is highly encouraging and underscores the clinical relevance of targeted TYK2 inhibition designed for maximal 24-hour target coverage.”

Fall Clinical Data* Highlights:

- **High-rate of scalp clearance:** Over 80% of patients in ONWARD3 maintained clear or almost clear scalp skin (scalp-specific Physician Global Assessment [ss-PGA] 0/1) at 48 weeks.
- **Rapid, robust and sustained itch relief:** In ONWARD 1/2, approximately one-third of

patients—including those with moderate-to-severe scalp disease (ss-PGA ≥ 3)—achieved clinically meaningful itch reduction (≥ 4 -point NRS improvement) as early as Week 2. By Week 16, about 40% reached complete itch resolution (NRS 0) and approximately 60% reported minimal or no itch (NRS 0/1). In ONWARD3, nearly 80% of patients sustained clinically meaningful itch reduction through Week 48.

- **Early, durable quality-of-life improvements:** Approximately 50% of patients in ONWARD 1/2 achieved a Dermatology Life Quality Index (DLQI) score of 0 or 1 by Week 12, reflecting minimal to no impact of psoriasis on daily activities. In ONWARD3, more than 70% of patients maintained DLQI 0/1 at 48 weeks.
- **Rapid crossover convergence:** Patients switching from placebo or apremilast achieved rapid improvements across primary and key secondary endpoints, comparable to those continuously treated at Week 48

*ONWARD3: N=1,509, data reported from non-responder imputation analysis in 773 patients from envudeucitinib arms who received up to 48 weeks of continuous treatment (24 weeks in ONWARD1/2 and up to 24 weeks in ONWARD3). ONWARD1/2: N=1771 (envudeucitinib n=459, 433; placebo n=230, 211, apremilast n=223, 215, respectively).

Treatment with envudeucitinib was generally well tolerated in the ONWARD program. No new safety signals were observed with long-term exposure in ONWARD3.

“The dataset presented at Fall Clinical further demonstrates envudeucitinib’s highly competitive clinical profile, reinforcing the strength of our precision engineering approach and its potential to become a leading therapy in the oral psoriasis market,” said Martin Babler, Chief Executive Officer of Alumis. “With our fourth-quarter 2026 NDA submission firmly on track, our organization is focused on regulatory execution and building the foundation designed to bring this next-generation therapy to patients.”

About the Phase 3 ONWARD Clinical Program

The Phase 3 ONWARD clinical program includes two parallel global, multicenter, 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.

Patients completing Week 24 of ONWARD1 or ONWARD2 were eligible to enter the ONWARD3 ([NCT06846541](#)) study, an ongoing long-term extension study assessing durability, maintenance of response, and long-term safety. In ONWARD3, all patients received open-label envudeucitinib treatment for the first 24 weeks, regardless of their treatment assignment in ONWARD1 and 2. To assess durability and maintenance of response, the first 200 patients achieving PASI 75 at Week 24 in ONWARD3 could enter a 24-week randomized withdrawal period (RWP), in which they were randomized to receive either blinded envudeucitinib or placebo, and reassigned to open-label envudeucitinib upon loss of response or completion of the RWP, whichever occurred first. Patients not entering the randomized withdrawal period continued to receive open-label envudeucitinib treatment. ONWARD3 is designed to provide up to 96 weeks of long-term safety and efficacy data.

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 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, 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; the therapeutic potential of TYK2 inhibition across immune-mediated diseases and the potential multi-indication opportunity for envudeucitinib; the advancement of Alumis' clinical pipeline; the potential for envudeucitinib to be a leading oral therapy in plaque psoriasis; 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; 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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