



Envudeucitinib Long-term Data Positioned to Set a New Standard for Plaque Psoriasis Treatment, Delivering Highest Reported PASI 100 Skin Clearance Among Oral Therapies

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- ONWARD3 data show 54% of patients reached complete skin clearance (PASI 100) after 48 weeks of continuous envudeucitinib treatment –*
- Favorable long-term safety and tolerability profile remained consistent with previously reported data –*
- On track to submit a New Drug Application to FDA in 4Q 2026 –*

SOUTH SAN FRANCISCO, Calif., Aug. 10, 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 topline results from the ongoing ONWARD3 long-term extension (LTE) study. Data confirm envudeucitinib delivered leading skin clearance and the highest reported Psoriasis Area and Severity Index (PASI) 100 response rates among existing and investigational oral therapies. Envudeucitinib is an investigational, next-generation oral TYK2 inhibitor precision-engineered for maximal 24-hour target inhibition.

“Envudeucitinib delivered consistently high rates of skin clearance in the Phase 3 trials, and the long-term data show that the vast majority of patients maintained these strong responses through 48 weeks, with the number of patients achieving completely clear skin continuing to rise over time,” said Dr. Mark Lebwohl, Dean for Clinical Therapeutics at the Icahn School of Medicine at Mount Sinai. “These data, coupled with a consistent safety profile, suggest that envudeucitinib can deliver the durable, reliable disease control physicians and patients are seeking from an oral therapy.”

A total of 1,509 patients entered ONWARD3 from ONWARD1 or ONWARD2, reflecting a robust rollover rate of >85%. A non-responder imputation (NRI) analysis was conducted in 773 of these patients from the envudeucitinib arms who received up to 48 weeks of continuous treatment (24 weeks in ONWARD1/2 and up to 24 weeks in ONWARD3). Topline results include:

- 75% and 54% of patients achieved PASI 90 and PASI 100, respectively
- Among patients who entered ONWARD3 with PASI 90 and PASI 100 responses, approximately 90% and 80%, respectively, sustained their skin clearance for the reported duration of the extension study

Results from a separate integrated NRI analysis across the ONWARD program (ONWARD1/2 and 3)—evaluating 890 patients originally randomized to envudeucitinib in ONWARD1/2, including those who did not transition into ONWARD3—demonstrated that 66% and 47% of patients who received 48 weeks of envudeucitinib achieved PASI 90 and PASI 100, respectively.

Treatment with envudeucitinib in ONWARD3 continued to be well tolerated, with a safety profile consistent with ONWARD1/2 and no new safety signals observed.

“Far too many people with psoriasis remain undertreated or untreated, and without meaningful skin clearance, this systemic disease continues to limit daily life,” said Leah M. Howard, J.D., President and CEO of the National Psoriasis Foundation. “We are excited for the potential of a new oral therapy that may offer the sustained control patients need to get back to living fully. Restoring those everyday moments is part of what real progress looks like.”

“These long-term data, including the robust 54% PASI 100 response, further validate the strength of envudeucitinib’s precision-engineered design for continuous, maximal TYK2 inhibition and underscore its highly competitive clinical profile,” said Dr. Jörn Drappa, Chief Medical Officer of Alumis. “This level of performance reinforces envudeucitinib’s potential to become a leading oral therapy for moderate-to-severe plaque psoriasis and a ‘pipeline-in-a-pill’ for immune-mediated diseases driven by IL-23, IL-17, and Type I interferon pathways.”

Alumis plans to present additional results from the ONWARD program at upcoming medical meetings and to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration seeking approval for envudeucitinib for the treatment of moderate-to-severe plaque psoriasis in the fourth quarter of this year. Topline data from the LUMUS Phase 2b trial of envudeucitinib in systemic lupus erythematosus is expected in the third quarter of 2026.

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 is advancing its clinical development via ONWARD3, an ongoing Phase 3 long-term

extension study in moderate-to-severe plaque psoriasis, and LUMUS, a potentially pivotal Phase 2b trial in systemic lupus erythematosus, with topline data anticipated in Q3 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. 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 fourth quarter of 2026, the potential for envudeucitinib to be a leading therapy 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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