



PRESS RELEASE

Egle Therapeutics Announces Positive Phase 1 Data for EGL-003, Showing Favorable Safety and Selective Treg Expansion in Healthy Volunteer Study

- *EGL-003, a selective IL-2 agonist, was well tolerated across all four dose cohorts.*
- *EGL-003 produced selective, dose-dependent Treg expansion without amplification of conventional CD4, CD8 or NK cell populations.*
- *Biomarker and pharmacodynamic data confirm functionally active, sustained Treg engagement, including findings consistent with skin-homing Treg migration.*
- *Data support advancement to a multiple ascending dose (MAD) proof-of-concept study in atopic dermatitis, planned to start in Q4 2026.*
- *Data presented today at the 35th EADV Congress in Vienna; Egle to host an investor and analyst webcast on October 1, 2026.*

Paris, France, September 30, 2026 – Egle Therapeutics (“Egle”), a clinical-stage biotechnology company pioneering precision medicines that modulate regulatory T cells (Tregs) to rebalance immune function in patients with autoimmune diseases, today announced positive results from its Phase 1 single ascending dose (SAD) study in healthy volunteers of EGL-003, the company’s Treg-selective interleukin-2 (IL-2) agonist being developed for autoimmune diseases, including atopic dermatitis. The data, which include safety, pharmacokinetic and pharmacodynamic findings across all four dose cohorts, are being presented at the 35th Congress of the European Academy of Dermatology and Venereology (EADV), taking place September 30 – October 3, 2026, in Vienna, Austria (presentation titled “EGL-003 First in Human study: An IL-2 Mutein Inducing Potent and Selective Amplification of Treg with Preferential Activation of Effector/Memory Skin Homing Tregs,” Abstract / ePoster AS-3660 / P1719).

“The Phase 1 data support the core biology behind EGL-003: potent, selective activation of Tregs, sustained pharmacodynamic activity and a favorable early safety profile,” said Kenji Hashimoto, MD, PhD, Chief Medical Officer of Egle Therapeutics. “The depth and durability of Treg expansion we observed, together with the functional and phenotypic markers of Treg activity, give us confidence in the mechanism as we move into our multiple ascending dose study in atopic dermatitis.”

The Phase 1 study enrolled 24 healthy volunteers across four dose levels (0.5, 1.5, 2.5 and 5 µg/kg), each receiving a single subcutaneous dose of EGL-003. All cohorts were assessed for PK and PD through Day 8, except the 2.5 µg/kg cohort, which was assessed through Day 56..

Favorable Safety and Tolerability

- No serious adverse events were reported at any dose.
- Injection-site reactions, the most common finding, were mild (Grade 1) and self-limited.
- Flu-like symptoms were limited to the two highest-dose cohorts and were mild, with the exception of one moderate case of headache at 2.5 µg/kg.

- All other adverse events were Grade 1.

Selective, Dose-Dependent and Sustained Treg Expansion

- EGL-003 produced dose-dependent expansion of total Tregs across all doses for up to 28 days without corresponding increases in conventional CD4, CD8 or NK cell populations.
- Across the SAD dose range, EGL-003 induced approximately 8- to 21-fold increases in activated (CD25 bright) Treg expansion.
- Egle observed dose-dependent, consistent upregulation of activation and suppressive-function markers on Tregs, including CD25, CTLA-4, FoxP3, ICOS, HLA-DR and proliferation marker Ki67.
- Plasma levels of the anti-inflammatory cytokine IL-10, an indicator of regulatory immune activity, increased with kinetics that paralleled Treg expansion.

Evidence Consistent with Skin-Homing Treg Migration

- Egle observed expansion of cutaneous lymphocyte antigen (CLA)-positive Tregs, a marker of skin-homing T cells, followed by a decline below baseline of this population in circulation, a kinetic pattern consistent with migration from the bloodstream into tissue.
- CLA-negative Tregs, by contrast, remained elevated in circulation.
- Egle believes these findings support the hypothesis that peripherally activated Tregs can traffic toward the skin, a mechanism the company plans to evaluate directly in patients. Disease-modification and maintenance-dosing hypotheses based on these findings require further clinical validation.

Advancing to a Multiple Ascending Dose Study in Atopic Dermatitis

- Based on the SAD safety and pharmacodynamic data, Egle plans to advance EGL-003 into a multiple ascending dose (MAD) proof-of-concept study, a double-blind, placebo-controlled, randomized trial in approximately 50 to 100 adults with moderate-to-severe atopic dermatitis.
- The starting regimen is 1.5 µg/kg every four weeks, with subsequent cohorts evaluating doses up to 5 µg/kg on a four- or two-week schedule based on emerging data.
- The primary endpoint is safety; secondary endpoints include the Eczema Area and Severity Index (EASI) and validated Investigator Global Assessment (vIGA), with exploratory endpoints assessing pharmacodynamic biomarkers in skin and blood.
- The study is planned to start in the fourth quarter of 2026, with preliminary efficacy data targeted for the second quarter of 2027, and a full assessment targeted for the fourth quarter of 2027.

“Atopic dermatitis affects more than 200 million people globally, and many patients do not achieve durable control with existing treatments,” said John Celebi, Chief Executive Officer of Egle Therapeutics. “These data reinforce our conviction that restoring immune balance upstream, rather than suppressing individual inflammatory pathways one at a time, is a differentiated approach worth pursuing. We look forward to generating clinical proof-of-concept data in atopic dermatitis and to sharing our progress with investors and the broader dermatology community.”

Webcast to Review the Data

Egle will host a webcast on October 1, 2026, discussing the SAD data in greater detail, featuring commentary from Stephan Weidinger, MD, PhD, Professor and Chair for Dermatology at Christian-Albrechts-University (Kiel) and Director of the Department of Dermatology and Allergy at University

Hospital Schleswig-Holstein, Campus Kiel, Germany. The webcast can be accessed [here](#), or via the Egle Therapeutics website (www.egle-tx.com) under “Events” in the “News” section.

About Atopic Dermatitis

Atopic dermatitis (AD) is a common, chronic inflammatory skin disease with significant patient burden, including itch, sleep disruption, visible lesions, and quality of life impacts, especially in moderate to severe cases. In the U.S. and EU combined, there are an estimated 21.2 million addressable moderate to severe AD patients. Current treatments span topicals, phototherapy, systemic immunomodulators, and targeted biologics/JAK inhibitors; however, many patients do not achieve sustained control, resulting in unmet needs for new treatment options that can provide long-term remission and quality of life gains.

About EGL-003

EGL-003 is a next-generation IL-2 mutein engineered for potent, selective activation of regulatory T cells while sparing conventional effector T cells. In its Phase 1 single ascending dose study in healthy volunteers, EGL-003 was well tolerated and produced selective, sustained Treg expansion. EGL-003 is being evaluated in atopic dermatitis, with a multiple ascending dose study planned to begin in Q4 2026, and has the potential to expand into additional autoimmune and inflammatory indications.

About Egle Therapeutics

Egle Therapeutics is a clinical-stage biotechnology company pioneering precision medicines that modulate regulatory T cells (Tregs) to rebalance immune function in patients with autoimmune diseases and cancer. The company’s proprietary technology enables highly selective IL-2 variant immuno-conjugates which are designed to overcome the efficacy and safety limitations of previous Treg-focused therapies. Its autoimmunity portfolio is led by EGL-003, an IL-2 agonist Treg engager currently being explored as a potential treatment for atopic dermatitis and other autoimmune diseases. For more information, visit www.egle-tx.com and follow us on LinkedIn.

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