

Almirall announces positive, top-line results from Phase 3 ADorable-1 trial

Lebrikizumab delivered significant skin clearance and improved disease severity in children with moderate-to-severe atopic dermatitis

- **ADorable-1 met co-primary efficacy endpoints, with 63% of paediatric patients achieving meaningful skin improvement (EASI-75) and 44% reaching clear or almost clear skin (IGA 0,1) at week 16.**
- **Key secondary endpoints showed significant itch relief (Pruritus NRS ≥ 4 point improvement), reduced overall disease severity (EASI-90) and improved quality of life (CDLQI ≥ 6 -Point Improvement) in children and adolescents with moderate-to-severe atopic dermatitis treated with lebrikizumab.**
- **Skin conditions can have a profound physical and emotional impact on people's lives¹, and Atopic Dermatitis (AD) peaks in childhood – with around 60% of cases appearing within the first year of life².**

BARCELONA, Spain. March, 16th, 2025 – Almirall, S.A. (ALM), a global biopharmaceutical company focused on medical dermatology, today announced positive, top-line results from the pivotal Phase 3 ADorable-1 trial evaluating efficacy and safety of lebrikizumab for children and adolescents with moderate-to-severe atopic dermatitis aged 6 months to <18 years. Lebrikizumab met both co-primary and key secondary endpoints, delivering near-complete skin clearance, reduced disease severity, itch relief and improved quality of life at Week 16.

Skin conditions can have a significant impact on people's lives, both physically and emotionally³. Atopic dermatitis is more prevalent in childhood than adulthood and typically begins early in life⁴, with most cases appearing by the first year of life (60%) or before 5 years of age (85%)⁵. The emotional impact of atopic dermatitis can disrupt crucial formative years, with disease burden increasing alongside severity and often leading to sleep disruption, school absenteeism, and difficulties in socializing⁶.

“At Almirall, we are committed to advancing skin science through a holistic approach to disease management, recognizing the profound effect skin conditions have on people's lives. We are excited about the positive, top-line results from the Phase 3 ADorable-1 trial and the meaningful impact they could have on children and adolescents and their life trajectories,” said Dr Karl Ziegelbauer, Chief Scientific Officer at Almirall.

“Children with atopic dermatitis still face considerable unmet needs, with persistent symptoms, limited treatment options, and a disease burden that grows with severity. There is a need for advanced treatment solutions, considering the specific challenges of younger patients and their families.”, said Prof Weidinger, Department of Dermatology, Allergology and Venerology at University Hospital Schleswig-Holstein, Kiel, Germany.

In ADorable-1, 363 inadequately controlled patients with moderate-to severe AD aged 6 months to <18 years were randomized to receive a weight-based dose of lebrikizumab or placebo every two weeks or every four weeks. Topical corticosteroids were required two weeks before randomization and throughout the 16-week study but could be decreased or stopped once patients achieved IGA 2 or less. The co-primary endpoints in ADorable-1 were EASI-75 and IGA 0,1 at Week 16. Key secondary endpoints included an even greater clinical improvement in disease severity (EASI-90), itch relief (Pruritus NRS ≥ 4 -point improvement) and quality of life (CDLQI ≥ 6 -Point Improvement).

Key efficacy results in ADorable-1 at Week 16

- **Reduced disease severity:** 63% of paediatric patients treated with lebrikizumab achieved a significant improvement in disease severity (EASI-75), compared with 22% of patients receiving placebo.
- **Near-complete skin clearance:** 44% of children and adolescents treated with lebrikizumab reached clear or almost clear skin (IGA 0,1) by week 16, compared to 15% of those treated with placebo. 39% of patients receiving lebrikizumab achieved an even greater clinical improvement in disease severity (EASI-90), compared to 11% of those receiving placebo.
- **Significant symptom relief:** lebrikizumab showed significant itch relief in 35% of patients aged 6 years and older with score ≥ 4 at baseline (Pruritus NRS ≥ 4 point improvement), in contrast with 6% of patients treated with placebo.
- **Improved quality of life:** 62% of paediatric patients treated with lebrikizumab, compared with 36% of those treated with placebo, saw an improvement in quality of life (CDLQI ≥ 6 -Point Improvement), demonstrating benefits across a broad range of key health-related indicators, including symptoms, emotional impact, leisure activities, school or holidays, personal relationships, sleep, and treatment burden.

The results from Phase 3 ADorable-1 trial are consistent with the established safety profile of lebrikizumab, approved in Europe for adult and adolescent patients older than 12 years old, with no new safety signals observed. The most common adverse events in the study reported by 5% of participants were upper respiratory tract infections and nasopharyngitis, with no numerical imbalance between treatment groups. Injection site reactions were reported similarly in both the lebrikizumab and placebo arms. ADorable-1 results provide important evidence to advance our paediatric development program for lebrikizumab in moderate-to-severe atopic dermatitis.

The ADorable clinical program is ongoing. Additional results from ADorable-1 and ADorable-2, a 52-week extension study of patients enrolled in ADorable-1, will be disclosed later this year. Almirall continues to show its commitment to science and its efforts to address patient needs through a new Phase 3 trial of lebrikizumab in patients with nummular eczema and multiple ongoing studies that will further extend the evidence base for its biologics treatments.

Almirall continues to strengthen its leadership in medical dermatology through sustained investment in science, cutting edge R&D capabilities, and a pipeline designed to tackle some of the most significant unmet needs in skin health. Leveraging strong scientific expertise, global collaborations and partnerships with dermatologists, the company is advancing a diverse portfolio that uses novel modalities to address debilitating conditions such as hidradenitis suppurativa, alopecia areata, and atopic dermatitis. Its early-stage clinical program currently includes three ongoing PoC/Phase II studies, with three additional PoC trials planned for 2026, and the progression of a bispecific antibody targeting IL13 and OX40L into Phase I.

Almirall has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including atopic dermatitis, in Europe, while Eli Lilly and Company retains rights for development and commercialization in the U.S. and the rest of the world outside Europe.

About ADorable-1 trial

ADorable-1 is a multicenter, randomized, double blind, placebo-controlled phase 3 trial in 363 children and adolescents with moderate-to-severe atopic dermatitis that evaluated lebrikizumab vs placebo on top of standardized low-to-medium potency topical corticosteroids (TCS). Coprimary efficacy endpoints at Week 16 are IGA 0/1 with ≥ 2 point improvement and EASI75, with key secondary endpoints including EASI90, pruritus NRS, cDLQI, and others.

ADorable-1 is part of the ADorable clinical program designed to assess lebrikizumab efficacy and safety for paediatric patients in two phase 3 clinical trials: ADorable-1 and ADorable-2.

About Lebrikizumab

Lebrikizumab (LEB) is a monoclonal antibody that selectively targets the cytokine IL-13 with high affinity, blocking its downstream signaling^{7,8,9,10,11}, while avoiding broader immunosuppression^{12,13} and preserving IL-13

physiological clearance¹⁴. Lebrikizumab is approved in Europe, under the brand name Ebglyss®, for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy¹⁵.

About Almirall

Almirall is a global biopharmaceutical company dedicated to medical dermatology. We closely collaborate with leading scientists, healthcare professionals, and patients to deliver our purpose: *to transform the patients' world by helping them realize their hopes and dreams for a healthy life*. We are at the forefront of science to deliver ground-breaking, differentiated medical dermatology innovations that address patients' needs.

Almirall, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM, total revenue in 2025: €1114.5 MM, over 2100 employees globally). Almirall products help to improve the lives of patients every day and are available in over 100 countries.

For more information, please visit <https://www.almirall.com/>

Corporate Communications:

Corporate.communication@almirall.com

Phone: (+34) 659 614 173

Investor Relations

investor.relations@almirall.com

Phone: (+34) 93 291 30 87

Legal warning

This document includes only summary information and is not intended to be exhaustive. The facts, figures and opinions contained in this document, in addition to the historical ones, are "forward-looking statements". These statements are based on the information currently available and the best estimates and assumptions that the company considers reasonable. These statements involve risks and uncertainties beyond the control of the company. Therefore, actual results may differ materially from those declared by such forward-looking statements. The company expressly waives any obligation to revise or update any forward-looking statements, goals or estimates contained in this document to reflect any changes in the assumptions, events or circumstances on which such forward-looking statements are based, unless required by the applicable law.

¹ Skin diseases as a public health priority [https://apps.who.int/gb/ebwha/pdf_files/EB156/B156_\(24\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB156/B156_(24)-en.pdf)

² Weidinger S, Simpson EL, Silverberg JI, et al. Burden of atopic dermatitis in paediatric patients: an international cross-sectional study. *Br J Dermatol.* 2024;190(6):846-857. doi:10.1093/bjd/ljad449.

³ Skin diseases as a public health priority [https://apps.who.int/gb/ebwha/pdf_files/EB156/B156_\(24\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB156/B156_(24)-en.pdf)

⁴ Silverberg JI. Comorbidities and the impact of atopic dermatitis. *Ann Allergy Asthma Immunol.* 2019;123(2):144-151. doi:10.1016/j.anai.2019.04.020

⁵ Weidinger S, Simpson EL, Silverberg JI, et al. Burden of atopic dermatitis in paediatric patients: an international cross-sectional study. *Br J Dermatol.* 2024;190(6):846-857. doi:10.1093/bjd/ljad449.

⁶ Weidinger S, Simpson EL, Silverberg JI, et al. Burden of atopic dermatitis in paediatric patients: an international cross-sectional study. *Br J Dermatol.* 2024;190(6):846-857. doi:10.1093/bjd/ljad449.

⁷ Moyle M, Cevikbas F, Harden JL, Guttman-Yassky E. Understanding the immune landscape in atopic dermatitis: the era of biologics and emerging therapeutic approaches. *Exp Dermatol.* 2019;28(7):756-768.

⁸ Okragly AJ, Ryuzoji A, Wulur I, Daniels M, Van Horn RD, Patel CN, et al. Binding, neutralization and internalization of the interleukin-13 antibody, lebrikizumab. *Dermatol Ther (Heidelb).* 2023;13(7):1535-1547.

⁹ Ultsch M, Bevers J, Nakamura G, et al. Structural basis of signaling blockade by anti-IL-13 antibody lebrikizumab. *J Mol Biol.* 2013;425(8):1330-1339.

¹⁰ Tsuji G, Yamamura K, Kawamura K, Kido-Nakahara M, Ito T, Nakahara T. Novel therapeutic targets for the treatment of atopic dermatitis. *Biomedicines.* 2023;11:1303.

¹¹ Furue M, Ulzii D, Nakahara T, Tsuji G, Furue K, Hashimoto-Hachiya A, et al. Implications of IL-13Rα2 in atopic skin inflammation. *Allergol Int.* 2020;69:412-416.

¹² Moyle M, Cevikbas F, Harden JL, Guttman-Yassky E. Understanding the immune landscape in atopic dermatitis: the era of biologics and emerging therapeutic approaches. *Exp Dermatol.* 2019;28(7):756-768.

¹³ Gonçalves F, Freitas E, Torres T. Selective IL-13 inhibitors for the treatment of atopic dermatitis. *Drugs Context*. 2021;10:2021-1-7. doi:10.7573/dic.2021-1-7.

¹⁴ Moyle M, Cevikbas F, Harden JL, Guttman-Yassky E. Understanding the immune landscape in atopic dermatitis: the era of biologics and emerging therapeutic approaches. *Exp Dermatol*. 2019;28(7):756-768.

¹⁵ European Medicines Agency (EMA). Ebglyss: EPAR—Product Information. Accessed February 7, 2026. https://www.ema.europa.eu/en/documents/product-information/ebglyss-epar-product-information_en.pdf