Press Release

For media and investors only
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New data show Almirall´s EBGLYSS® (lebrikizumab) provided sustained disease control for up to three years in more than 80% of adults and adolescents with moderate-to-severe atopic dermatitis

- **Monthly lebrikizumab maintenance dosing sustained clear or almost-clear skin for up to three years in the vast majority (more than 80%) of ADvocate 1 and 2 responders**
- **Nearly 87 percent of patients taking lebrikizumab did not require either high-potency topical corticosteroids or systemic treatments during the three-year period**
- **The safety profile at three years was consistent with the previously published two-year results**

BARCELONA, Spain. September 25, 2024. – More than 80 percent of adults and adolescents with moderate-to-severe atopic dermatitis who responded to lebrikizumab treatment at Week 16 in the ADvocate 1 and 2 monotherapy trials and continued treatment for **up to three years experienced sustained skin clearance with monthly maintenance dosing**. Almirall S.A. (BME: ALM) announced these **new long-term results from the ADjoin long-term extension study**, which will be presented as a late breaker at the European Academy of Dermatology and Venereology (EADV) Congress from Sept. 25-28 in Amsterdam, Netherlands.[1]

Lebrikizumab is an interleukin-13 (IL-13) inhibitor that selectively blocks IL-13 signaling with high binding affinity.[2,3,4,] The cytokine IL-13 is key in atopic dermatitis, driving the type-2 inflammatory cycle in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.[5,6]

"*Moderate-to-severe atopic dermatitis imposes a significant burden on patients, affecting their quality of life and overall wellbeing*," said **Prof. Dr. med. Diamant Thaçi**, Director at the Institute and Comprehensive Centre for Inflammation Medicine, in Lübeck, Germany. "*These new three-year clinical data demonstrate the potential this biologic treatment has to provide sustained relief from this disease, offering long-term benefits to people living with this chronic and relapsing condition*."

Patients taking lebrikizumab who completed 52 weeks in ADvocate 1 or 2 could enroll in ADjoin for an additional 100 weeks of continued treatment (up to 152 weeks of continuous treatment). Patients in this analysis of the long-term extension trial received treatment either 250 mg every two weeks (Q2W) or once monthly (Q4W). The approved maintenance dose of lebrikizumab is 250 mg Q4W. These data presented are part of ADjoin, the long-term extension study of the lebrikizumab trials, and include participants who responded to lebrikizumab treatment at Week 16 from ADvocate 1 and ADvocate 2.[1]

- 84 percent of these patients taking lebrikizumab once monthly and 83 percent taking

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lebrikizumab every two weeks maintained clear or almost-clear skin (IGA 0,1) at three years.[1]

- 87 percent of these patients taking lebrikizumab once monthly and 79 percent taking lebrikizumab every two weeks achieved or maintained at least 90 percent improvement in disease extent and severity (EASI-90) at three years.[1]
- 83 percent of these patients taking lebrikizumab once monthly and 91 percent taking lebrikizumab every two weeks did not require either high-potency topical corticosteroids or systemic treatments.[1]

"*These latest clinical data for lebrikizumab show the potential of this innovative medicine to provide sustained improvement of moderate-to-severe atopic dermatitis, a chronic and often debilitating condition*," said **Volker Koscielny, M.D., Chief Medical Officer at Almirall**. "*The data can help inform clinical decision-making and are reassuring, as they show that the vast majority of patients who respond to the treatment will continue to respond over time*."

The safety profile of these patients taking lebrikizumab in ADjoin was consistent with previous lebrikizumab studies, and no new safety signals were observed up to three years of treatment. The majority of adverse events were mild or moderate. Less than three percent of patients experienced adverse events leading to treatment discontinuation. The most common side effects of lebrikizumab were conjunctivitis, injection site reactions and shingles (herpes zoster).[1]

Additional data from this clinical study is underway, with results to be presented at future congresses.

Lebrikizumab was approved in the European Union and the UK in 2023, as well as in Japan, Switzerland, and the U.S. in 2024. It is available for prescription in Germany, the UK, Norway, Denmark, Spain and the Czech Republic.

"*Without adequate treatment, atopic dermatitis can leave people struggling with uncontrolled symptoms*," said **Mark Genovese, M.D., senior vice president of Immunology Development at Lilly**. "*Lebrikizumab selectively targets IL-13, one of the main drivers of inflammation in eczema. These three-year data demonstrate that lebrikizumab given once monthly provides sustained symptom relief for patients who need it most*."

Almirall has the exclusive rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including eczema, in Europe. Almirall's partner Lilly has the rights for development and commercialization of this biologic in the U.S. and the rest of the world outside Europe.

About ADjoin

ADjoin (NCT04392154) evaluated the long-term safety and efficacy of EBGLYSS treatment in patients with moderate-to-severe atopic dermatitis for up to 100 weeks (up to 152 weeks of continuous treatment with the parent studies). Patients taking EBGLYSS who completed any of the parent studies (ADvocate 1 and 2, ADhere, ADore, ADopt-VA) were able to enroll in ADjoin. The ADhere parent study includes patients taking topical corticosteroids with EBGLYSS as a combination therapy. Patients could also enroll directly into ADjoin without participating in a parent study. Patients in this analysis of the long-term extension trial received either EBGLYSS 250 mg every two weeks or once monthly.[1]

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About EBGLYSS (lebrikizumab)

Lebrikizumab is a monoclonal antibody that selectively targets and neutralizes IL-13 with high binding affinity and a slow dissociation rate.[3,4,7] It binds to the IL-13 cytokine at an area that overlaps with the binding site of the IL-4Rα subunit of the IL-13Rα1/IL-4Rα heterodimer, preventing formation of this receptor complex and inhibiting IL-13 signaling.[5] IL-13 is implicated as a primary cytokine tied to the pathophysiology of eczema, driving the type-2 inflammatory loop in the skin, and lebrikizumab selectively targets IL-13.[7]

The Phase 3 program consists of five key global studies evaluating over 1,300 patients, including two monotherapy studies (ADvocate 1 and 2), a combination study with topical corticosteroids (ADhere), as well as long-term extension (ADjoin) and adolescent open label (ADore) studies. Further data results from ADmirable and ADapt are expected to be shared in 2024 and early 2025.

About Almirall

Almirall is a global pharmaceutical 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 2023: €898.8 MM, 1900 employees globally). Almirall products help to improve the lives of patients every day and are available in over 100 countries.

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