

Barcelona, September 25<sup>th</sup> 2024

## **OTHER RELEVANT INFORMATION**

**New data show Almirall's EBGLYSS<sup>®</sup> (lebrikizumab) provided sustained disease control for up to three years in more than 80% of adults and adolescents with moderate-to-severe atopic dermatitis**

In accordance with the Securities Markets and Investment Services Law, Almirall S.A. ("Almirall") announces the following:

- 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.

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.

Lebrikizumab is an interleukin-13 (IL-13) inhibitor that selectively blocks IL-13 signaling with high binding affinity. 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.

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.

- 84 percent of these patients taking lebrikizumab once monthly and 83 percent taking lebrikizumab every two weeks maintained clear or almost-clear skin (IGA 0,1) at three years.
- 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.
- 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.

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).

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.

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.

### **About EBGLYSS (lebrikizumab)**

Lebrikizumab is a monoclonal antibody that selectively targets and neutralizes IL-13 with high binding affinity and a slow dissociation rate. It binds to the IL-13 cytokine at an area that overlaps with the binding site of the IL-4R $\alpha$  subunit of the IL-13R $\alpha$ 1/IL-4R $\alpha$  heterodimer, preventing formation of this receptor complex and inhibiting IL-13 signaling. 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.

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.

Sincerely,

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