Press Release

EBGLYSS® (lebrikizumab) receives positive CHMP opinion for moderate-to-severe atopic dermatitis

- **Lebrikizumab is an investigational monoclonal antibody that binds to IL-13 protein with high affinity and inhibits its downstream signaling**
- **Positive opinion is based on Phase 3 studies which showed long-term response in skin clearance and itch control**

BARCELONA, Spain. September, 15th 2023 – Almirall S.A. (BME: ALM) today announced that **the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending the marketing authorization of EBGLYSS (lebrikizumab**) for the treatment of adult and adolescent patients (12 years and older with a body weight of at least 40 kg) with moderate-to-severe atopic dermatitis, who are candidates for systemic therapy.

The positive CHMP opinion is now being reviewed by the European Commission (EC). The approval of this biologic in the European Union is expected in approximately two months and its launch in the first European country could take place soon after.

Results from the Phase 3 clinical development program showed most patients (80 percent) who responded* to treatment with lebrikizumab at Week 16 weeks maintained skin clearance and itch relief through one year of treatment with monthly maintenance dosing.

"Atopic dermatitis, commonly known as atopic eczema, can have a profound impact on the quality of life for those it affects. Lebrikizumab's targeted mechanism of action inhibits IL-13 signaling. In clinical trials, it helped patients control their disease and maintain those results long term, over 52 weeks. Additionally, its monthly maintenance dosing regimen offers convenience and flexibility, benefiting both patients and healthcare providers. The potential inclusion of this treatment in the range of options against atopic dermatitis means a significant stride toward enhancing the quality of life of individuals struggling with this challenging skin condition" said **Prof. Alan Irvine**, dermatologist in Children's Health Ireland and St. James's Hospital, Dublin & Professor in Dermatology, Trinity College Dublin.

"The positive CHMP recommendation for EBGLYSS in moderate to severe AD represents a significant milestone in bringing a next-generation biologic therapy to people living with atopic dermatitis, providing a much needed additional treatment option. We are confident that EBGLYSS, thanks to its selective mechanism of action, proven long-term efficacy and patient friendly monthly maintenance dosing has the potential to become a first-line treatment for moderate-to-severe atopic dermatitis." said **Karl Ziegelbauer**, Chief Scientific Officer at Almirall.

The cytokine IL-13 is key in atopic dermatitis, driving the type-2 inflammatory loop in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.[1-6] Lebrikizumab binds to IL-13 protein with high affinity and specifically inhibits its downstream signaling.[7-8]

The CHMP opinion is based on three pivotal Phase 3 studies† including ADvocate 1 and ADvocate 2, evaluating lebrikizumab as monotherapy, and ADhere, assessing lebrikizumab in combination with topical corticosteroids (TCS), in adult and adolescent patients with moderate-to-severe atopic dermatitis. At Week 16, more than 50 percent of patients with moderate-to-severe atopic dermatitis experienced at least 75 percent reduction in disease

severity (EASI-75) when receiving lebrikizumab monotherapy in the ADvocate studies and nearly 70 percent of patients receiving lebrikizumab combined with standard-of-care TCS achieved EASI-75 in the ADhere trial.

The Phase 3 clinical development program also evaluated the safety profile of lebrikizumab. Most adverse events (AE) across the studies were mild or moderate in severity non serious, and did not lead to treatment discontinuation. The most common adverse reactions were conjunctivitis, injection site reactions, conjunctivitis allergic and dry eye.

Almirall has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including atopic dermatitis, in Europe. Eli Lilly and Company has exclusive rights for the development and commercialization of the product in the United States and the rest of the world, not including Europe. Almirall expects regulatory decisions for lebrikizumab in moderate-to-severe atopic dermatitis in additional European markets, including the United Kingdom and Switzerland in 2024.

† More information about the Phase 3 studies: ADvocate 1: EudraCT Number 2019-002932-10; NCT04146363; ADvocate 2: EudraCT Number 2019-002933-12; NCT04178967; Adhere: EudraCT Number 2019-004300-34; NCT04250337

*Responders were defined as those achieving a 75% reduction in the Eczema Area and Severity Index from baseline (EASI-75) or an IGA 0 or 1 (“clear” or “almost clear”) with at least 2-point improvement and without rescue medication use at Week 16. At Week 16, responders were re-randomized to lebrikizumab 250 mg every two weeks or four weeks or placebo for an additional 36 weeks.

About lebrikizumab and Clinical Development Program

Lebrikizumab is an investigational, monoclonal antibody that binds IL-13 with high affinity to specifically prevent the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13.[7-8] The cytokine IL-13 is key in atopic dermatitis, driving the type-2 inflammatory loop in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.[1-6]

The lebrikizumab phase III 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.

About Almirall

Almirall is a global biopharmaceutical company focused on medical dermatology. We collaborate with scientists and healthcare professionals to address patients' needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life". We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1944 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has focused intensely on patients' needs. Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenue in 2022 was €878.5 MM.

For more information, please visit almirall.com

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