Press Release

Almirall receives European Commission approval of EBGLYSS® (lebrikizumab) for moderate-to-severe atopic dermatitis

- **Lebrikizumab is a monoclonal antibody that binds to IL-13 with high affinity, selectively inhibiting its downstream signalling[1-4]**
- **Following the European Commission approval, Germany is the first country where lebrikizumab will be available for prescription**
- **Lebrikizumab demonstrated early clinical efficacy and maintenance of response up to 2 years in both monotherapy and combination with topical corticosteroids[5-8] with monthly maintenance dosing for all patients[13]**

BARCELONA, Spain. November 17th, 2023 – Almirall S.A. (BME: ALM), a global biopharmaceutical company focused on medical dermatology, announced today that the **European Commission (EC) has approved 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 (AD), who are candidates for systemic therapy. Almirall will first start the commercial launch in Germany. The company will continue the rollout in further European countries throughout 2024.

Lebrikizumab is a monoclonal antibody that binds IL-13 with high affinity to specifically prevent the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signalling, thereby inhibiting the biological effects of IL-13.[1-4] 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.[2,9-12] Lebrikizumab represents a significant step forward in patients with moderate-to-severe AD not controlled with topical therapy due to its selective mechanism of action,[2] proven short and long-term efficacy and safety demonstrated up to 2 years[5-8] and a monthly maintenance dosing for all patients.[13]

"The EC approval of lebrikizumab for people suffering with moderate-to-severe AD provides another much-needed treatment option for this challenging disease. We are confident that due to its demonstrated short and long-term efficacy, with monthly maintenance dosing and a consistent safety profile, it has the potential to become a first-line biologic treatment. This regulatory milestone again highlights Almirall's commitment to develop innovative treatments that can make a meaningful difference in the lives of people with skin diseases," stated **Dr. Volker Koscielny, Chief Medical Officer at Almirall.**

"The arrival of novel biologic treatments is marking a new paradigm in the management of atopic dermatitis. The approval of lebrikizumab represents a leap forward in our ability to provide patients with an effective therapeutic option with demonstrated safety profile. For healthcare professionals, it opens the door to improve the management of the disease and create a meaningful impact in the lives of our atopic dermatitis patients, offering new hope and improved prospects for their wellbeing," stated **Stephan Weidinger, MD, Ph.D.** Professor of Dermatogenetics at the Christian-Albrechts-University and Vice-Head of the Department of Dermatology at the University Hospital Schleswig-Holstein, Campus Kiel, Germany.

The approval 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. Lebrikizumab demonstrated early clinical efficacy in monotherapy at week 16,[5] reducing disease extent and severity by at least 75% (EASI-

75) in almost 6 out of 10 patients. In combination with topical corticosteroids,[6] this was achieved in almost 7 out of 10 patients. Nearly 80% of Week 16 responders* who continued treatment with lebrikizumab both as monotherapy and in combination with TCS for up to two years experienced sustained skin clearance, itch relief and reduced disease severity with monthly maintenance dosing.[8]

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 and did not lead to treatment discontinuation. The most common adverse reactions were conjunctivitis, injection site reactions, allergic conjunctivitis, 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.

*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.

About lebrikizumab Clinical Development Program

The lebrikizumab 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.

About Atopic Dermatitis

AD is a non-contagious chronic, inflammatory disease of the skin characterized by recurrent inflammation of the skin associated with intense pruritus or itching. Beyond the evident physical manifestations such as dryness, itchiness, redness, and inflammation, this condition exerts profound emotional effects that can significantly disrupt the academic, social, and professional lives of those affected.[14] With an estimated prevalence of up to 4.4% among adults in the EU, the incidence of AD appears to have increased in recent decades, with approximately 20-30% of patients having moderate-to-severe disease.[15-17]

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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