Barcelona, 17th November 2023

OTHER RELEVANT INFORMATION

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

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

- 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]

Almirall S.A., 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 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

Sincerely,

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*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.

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