Barcelona, September 15th 2023

OTHER RELEVANT INFORMATION

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

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

Today, 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.

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, nonserious, 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.

Sincerely,

Pablo Divasson del Fraile
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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. At Week 16, responders were re-randomized to lebrikizumab 250 mg every two weeks or four weeks or placebo for an additional 36 weeks.

**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.

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.

Legal warning

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