

Barcelona, 28th November 2022

OTHER RELEVANT INFORMATION

Almirall announces EMA acceptance for filing of Marketing Authorization Application (MAA) for lebrikizumab in atopic dermatitis

In accordance with Securities Markets Law Almirall, S.A. (“Almirall”) announce the following:

- Approval in Europe is expected in the second half of 2023
- The EMA application is based on the analysis of Phase III studies ADvocate 1&2 and ADhere
- Atopic dermatitis (AD) is a chronic, inflammatory skin disease. Up to 4.4% of adults in EU are affected, the prevalence appears to have increased over the past decades

Almirall, S.A. (ALM), a global biopharmaceutical company focused on skin health, today announced that the European Medicines Agency (EMA) has accepted the filing of the Marketing Authorization Application (MAA) for lebrikizumab for the treatment of moderate to severe atopic dermatitis.

The MAA dossier filing is based on three pivotal Phase III studies: ADvocate 1 and ADvocate 2, evaluating lebrikizumab as monotherapy in adult and adolescent patients with moderate-to-severe AD, and ADhere, assessing lebrikizumab in combination with topical corticosteroids (TCS). In the maintenance phase of the two monotherapy trials (ADvocate 1&2), lebrikizumab provided robust and durable improvements in skin clearance and itch for patients who achieved a clinical response* at Week 16 through one year of treatment. Results also demonstrated efficacy with every four-week dosing —after a 16-week induction period with lebrikizumab every two weeks—was similar to the efficacy observed for every two-week dosing.

Almirall has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including AD, in Europe. Eli Lilly and Company has exclusive rights for the development and commercialization of lebrikizumab in the United States and the rest of the world, not including Europe.

About Atopic Dermatitis

Atopic dermatitis (AD), or atopic eczema, is a non-contagious chronic, inflammatory disease of the skin characterized by recurrent inflammation of the skin associated with intense pruritus (severe itching). Apart from the evident physical effects (dry, itchy, red, and inflamed skin), this skin disease causes severe emotional effects that can have a big impact on the academic, social, and/or work life of patients with AD. Up to 4.4% of adults in EU are affected, the

prevalence appears to have increased over the past decades, and approximately 30% of adult patients have moderate-to-severe disease.

*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 a 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

Lebrikizumab is a novel, investigational, monoclonal antibody designed to bind IL-13 with high affinity, slow disassociation rate and high potency to specifically prevent the formation of the IL-13R α 1/IL-4R α heterodimer complex and subsequent signalling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion. AD is an IL-13 dominant disease in which IL-13 drives skin barrier dysfunction, itch, skin thickening, and susceptibility to infection.

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