Press Release

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

- **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[1,2]**

BARCELONA, Spain. October 28, 2022 – 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.

"Today marks the first step of the regulatory process in Europe of lebrikizumab, which we believe it has the potential to become a best-in-class treatment for atopic dermatitis. Upon approval by the EMA, patients with AD would have a new treatment option with a favourable safety and efficacy profile. At Almirall, we continue to work towards the market launch of this potential breakthrough treatment with the aim of fulfilling our purpose of improving patients' lives", stated **Karl Ziegelbauer, Ph.D.,** Almirall's Chief Scientific Officer**.**

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.

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* More information about the Phase III 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 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.[1,2]

*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-13Rα1/IL-4Rα heterodimer complex and subsequent signalling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion[3,4]. AD is an IL-13 dominant disease in which IL-13 drives skin barrier dysfunction, itch, skin thickening, and susceptibility to infection.[5,6,]

About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's 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 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2021 were 836.5 million euros.

For more information, please visit almirall.com

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