

Barcelona, June 7th 2022

OTHER RELEVANT INFORMATION

Eight out of Ten Patients Maintained Skin Clearance at One Year in Lebrikizumab Atopic Dermatitis Monotherapy Trials

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

- 80% of lebrikizumab responders maintained improvements in skin clearance and disease severity at 52 weeks; lasting improvements in itch were also observed
- Data supported both once every two week and once every four week maintenance dosing, with consistent and durable responses

Almirall S.A. today announced topline results from one-year analyses of the efficacy and safety of lebrikizumab, an investigational IL-13 inhibitor for the treatment of patients with moderate-to-severe atopic dermatitis (AD). The new findings from the Phase 3 clinical trials (ADvocate 1 and 2) showed eight out of ten patients who achieved clinical response (EASI-75) with lebrikizumab monotherapy at 16 weeks maintained skin clearance at one year of treatment with the once every two weeks or four weeks regimen. Additionally, patients treated with lebrikizumab maintained itch relief across the two trials over the one-year period. These results build upon positive data from the 16-week, double-blind, placebo-controlled part of the ADvocate program.

AD, or atopic eczema, is a chronic, relapsing, heterogenous skin disease characterized by intense itching, dry skin and inflammation that can be present on any part of the body. Lebrikizumab is a novel, monoclonal antibody (mAb) that binds to the interleukin-13 (IL-13) protein with high affinity to specifically prevent the formation of IL-13R α 1/IL-4R α (Type 2 receptor) which blocks downstream signaling through the IL-13 pathway. IL-13 plays the central role in AD, promoting Type 2 inflammation that drives skin barrier dysfunction, itch, skin thickening and infection.

In ADvocate 1, 79% of patients who received lebrikizumab every four weeks and 79% of patients who received lebrikizumab every two weeks maintained 75% or greater skin improvement (EASI-75) at one year of treatment. Additionally, 85% of patients who received lebrikizumab every four weeks and 77% of patients who received lebrikizumab every two weeks maintained EASI-75 response in ADvocate 2 at one year of treatment.

The frequency of adverse events and the overall safety profile among these patients treated with lebrikizumab were consistent with the induction phase of the trials as well as previous lebrikizumab studies in AD. No new safety signals were observed in this patient population.

With these data, Almirall plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for lebrikizumab in AD in the second half of 2022. Lilly also plans to submit an application to the U.S. Food and Drug Administration (FDA) this year, followed by submissions to other regulatory agencies around the world.

These studies are part of the comprehensive clinical development program for lebrikizumab in AD evaluating more than 2,000 patients. Full one-year results from the Phase 3 monotherapy studies will be disclosed at upcoming congresses and in publications in 2022. Additional Phase 3 clinical trials are enrolling for lebrikizumab in AD.

Almirall has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including AD, in Europe. Lilly has exclusive rights for development and commercialization of lebrikizumab in the United States and the rest of the world outside Europe.

Yours sincerely,

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