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OTHER RELEVANT INFORMATION

Almirall: Lebrikizumab demonstrated significant skin improvement and itch relief when combined with topical corticosteroids in people with atopic dermatitis in third Phase 3 study

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

- Study met all primary and key secondary endpoints
- Safety profile consistent with prior lebrikizumab studies in atopic dermatitis
- Global regulatory submissions to occur next year based on data from the Phase 3 clinical trial program

Lebrikizumab, an IL-13 inhibitor, significantly improved disease severity when combined with topical corticosteroids (TCS) in people with moderate-to-severe atopic dermatitis (AD) in a third pivotal Phase 3 trial (ADhere) announced today by Almirall S.A. By Week 16, the study met all primary and key secondary endpoints for patients on the lebrikizumab combination arm.

Lebrikizumab is a novel, investigational, monoclonal antibody (mAb) that binds soluble IL-13 with high affinity, has high bioavailability, a long half-life and blocks IL-13 signaling.¹⁻⁵ In people with AD, the IL-13 protein—a central pathogenic mediator in the disease—is overexpressed, driving multiple aspects of AD pathophysiology by promoting T-helper type 2 (Th2) cell inflammation and resulting in skin barrier dysfunction, itch, infection, flares and hard, thickened areas of skin.^{6,7}

The primary endpoints were Investigator Global Assessment (IGA) score of clear (0) or almost clear (1) skin with a reduction of at least two points from baseline and at least a 75 percent change from baseline in their Eczema Area and Severity Index (EASI) score, both at Week 16. Lebrikizumab in combination with TCS also achieved all key secondary endpoints versus placebo in patients with AD, including skin improvement, itch relief, improvement in interference of itch on sleep, and quality of life. Key secondary endpoints were measured by EASI, the Pruritus Numeric Rating Scale, Sleep-Loss due to Pruritus, and the Dermatology Life Quality Index.

Safety results in the 16-week placebo-controlled ADhere study were consistent with the 16-week period of the two monotherapy studies in the lebrikizumab Phase 3 program for AD. The most common adverse events (AEs) included conjunctivitis and headache for lebrikizumab-treated patients.

In August 2021, [top-line data](#) from ADvocate 1 and ADvocate 2 were announced by Almirall showing lebrikizumab as a monotherapy met primary and all key secondary endpoints including itch, interference of itch on sleep and quality of life at Week 16.

The detailed results from ADhere, along with data from two monotherapy Phase 3 trials, ADvocate

1 and ADvocate 2, are planned for future scientific congresses in 2022. Pending successful completion of the ongoing ADvocate 1 and ADvocate 2 monotherapy trials, Almirall and Eli Lilly and Company intend to begin EU, U.S. and other regulatory submissions next year.

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 rest of world outside Europe.

Yours sincerely,

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1 Moyle M, et al. *Exp Dermatol*. 2019;28(7):756-768.

2 Ultsch M, et al. *J Mol Biol*. 2013;425(8):1330-1339.

3 Zhu R, et al. *Pulm Pharmacol Ther*. 2017;46:88-98.

4 Simpson EL, et al. *J Am Acad Dermatol*. 2018;78(5):863-871.e11.

5 Okragly A, et al. Comparison of the Affinity and in vitro Activity of Lebrikizumab, Tralokinumab, and Cendakimab. Presented at the Inflammatory Skin Disease Summit, New York, November 3-6, 2021.

6 Bieber T. *Allergy*. 2020;75(1):54-62.