

Almirall Announces Initiation of Phase 3 Program Evaluating Lebrikizumab in Patients with Moderate-to-Severe Atopic Dermatitis

- **Two identical Phase 3 monotherapy studies expected to enroll a total of approximately 800 adult and adolescent patients ages 12 and older**
- **Topline results from the 16-week induction period expected in the first half of 2021**

Almirall, S.A. (ALM) today announced that Dermira, Inc. (NASDAQ: DERM) has started the Phase 3 study evaluating the safety and efficacy of lebrikizumab, in adult and adolescent patients ages 12 and older with moderate-to-severe atopic dermatitis, the most common form of eczema.

Lebrikizumab is a novel, investigational, monoclonal antibody designed to bind IL-13 with very high affinity, specifically preventing the formation of the IL-13R α 1/IL-4R α heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion. IL-13 is believed to be a central pathogenic mediator that drives multiple aspects of the pathophysiology of atopic dermatitis by promoting type 2 inflammation and mediating its effects on tissue, resulting in skin barrier dysfunction, itch, skin thickening and infection.

“The initiation of the Phase 3 study combined with the positive results of the Phase 2b study underscore our confidence and excitement around the potential of lebrikizumab for patients with moderate-to-severe atopic dermatitis,” said **Peter Guenter, chief executive officer of Almirall**. In June 2019, Almirall signed with Dermira a license agreement under which Almirall acquired exclusive license rights to develop lebrikizumab for the treatment or prevention of dermatology indications, including but not limited to atopic dermatitis, and commercialize lebrikizumab for the treatment or prevention of all indications in Europe. *“Almirall is fully committed to this partnership and to offering breakthrough treatments, like lebrikizumab, that have the potential to make a meaningful difference for patients living with severe skin conditions.”* Peter Guenter added.

“The positive results of our Phase 2b dose-ranging study suggest specifically targeting IL-13 with lebrikizumab has the potential to deliver a best-in-disease therapy for people living with moderate-to-severe atopic dermatitis,” said **Tom Wiggans, chairman and chief executive officer of Dermira**. *“Our Phase 3 clinical program is designed to confirm those findings and hopefully bring an important new treatment option to the millions of people living with this chronic and often debilitating disease. We expect to report findings from the 16-week induction period of the monotherapy studies in the first half of 2021.”*

Lebrikizumab Phase 3 Program

The lebrikizumab Phase 3 program includes two identical, randomized, double-blind, placebo-controlled, parallel-group Phase 3 studies designed to confirm the safety and efficacy of lebrikizumab as monotherapy in patients

with moderate-to-severe atopic dermatitis. The studies are expected to enroll a total of approximately 800 adult and adolescent patients ages 12 years and older with moderate-to-severe atopic dermatitis at approximately 200 sites in the United States, Europe and Asia.

Key patient inclusion criteria for the monotherapy studies include the presence of chronic atopic dermatitis for at least one year, an Investigator's Global Assessment (IGA) score of 3 or 4 (on a 5-point scale ranging from 0 to 4), an Eczema Area Severity Index (EASI) score of 16 or greater and body surface area (BSA) involvement of at least 10 percent at screening and baseline.

The studies will evaluate a 250 mg dose of lebrikizumab administered by subcutaneous injection every two weeks, following a loading dose of 500 mg administered at baseline (day 0) and week 2, compared to placebo for 16 weeks (the induction period). Following the end of the 16-week induction period, study patients who respond during the induction period (as evidenced by achievement of an IGA 0/1 response, representing a reduction of 2 or more points in IGA score from baseline to a final score of 0 (clear) or 1 (almost clear), or an EASI-75 response, representing an improvement in EASI score of at least 75 percent from baseline) will be re-randomized to one of the following treatment groups for an additional 36-week maintenance period:

- Group A: Lebrikizumab 250 mg given every two weeks;
- Group B: Lebrikizumab 250 mg given every four weeks; or
- Group C: Placebo given every two weeks.

Patients who do not achieve an IGA of 0/1 response or an EASI-75 response at week 16 and patients who do not maintain an EASI-50 response during the maintenance period will be assigned to receive lebrikizumab 250 mg as open-label treatment every two weeks through week 52.

The primary efficacy endpoint of the studies is the percentage of patients with an IGA 0/1 response from baseline to week 16.

Key secondary efficacy endpoints that will be evaluated during the 16-week induction period include: the percentage of patients achieving EASI-75; the percentage of patients achieving EASI-90; the percentage of patients with a pruritus (itch) numerical rating (NRS) score of at least 4 at baseline who achieve a reduction of at least 4 points; percentage changes in pruritus and sleep-loss scores; and change in BSA.

The company expects to report topline findings from the 16-week induction period in the first half of 2021. In addition to the two monotherapy studies, the company plans to include a study in the Phase 3 program that evaluates lebrikizumab when used in combination with topical corticosteroids. The impact of lebrikizumab treatment on quality of life will also be assessed across a number of additional measures.

About Atopic Dermatitis

Atopic dermatitis is the most common and severe form of eczema, a chronic inflammatory condition that can present as early as childhood and continue into adulthood. A moderate-to-severe form of the disease is characterized by rashes on the skin that often cover much of the body, as well as intense, persistent itching. The condition can have a negative impact on patients' mental and physical functioning, limiting their daily activities and health-related quality of life. Patients with moderate-to-severe atopic dermatitis have reported a larger impact on quality of life than patients with psoriasis.

About Lebrikizumab

Lebrikizumab is a novel, investigational, monoclonal antibody designed to bind IL-13 with very high affinity, specifically preventing the formation of the IL-13R α 1/IL-4R α heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion. IL-13 is believed to be a central pathogenic mediator that drives multiple aspects of the pathophysiology of atopic dermatitis by promoting type 2

inflammation and mediating its effects on tissue, resulting in skin barrier dysfunction, itch, skin thickening and infection.

About Dermira and Almirall Collaboration Agreement

In February 2019, Almirall, S.A. (BME: ALM) and Dermira (NASDAQ: DERM) entered into an option and license agreement under which Almirall acquired an option to obtain exclusive license rights to develop lebrikizumab for the treatment or prevention of dermatology indications, including but not limited to atopic dermatitis, and commercialize lebrikizumab for the treatment or prevention of all indications in Europe. Almirall exercised the option in June 2019. Under the terms of the agreement, Dermira received payments relating to the option and option exercise and is entitled to receive additional payments upon the achievement of certain development, regulatory and sales milestones, including in connection with the initiation of certain Phase 3 clinical studies, as well as royalty payments representing percentages of net sales of lebrikizumab in Europe.

About Almirall

Almirall is a leading skin-health focused pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients and future generations. Our efforts are focused on fighting skin health diseases and helping people feel their best. We support healthcare professionals in continuous improvement, bringing our innovative solutions where they are needed.

The company, founded almost 75 years ago and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its shareholders and its decision to help others by understanding their challenges and using Science to improve solutions for real life. Total revenues in 2018 were 811 million euros. Almirall has more than 1,800 employees.

For more information, please visit almirall.com [linkedin.com/company/almirall](https://www.linkedin.com/company/almirall)

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