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Almirall and Dermira Enter into Option and License Agreement for European Rights to Lebrikizumab

- **Almirall acquires option to license rights to develop and commercialize lebrikizumab for atopic dermatitis in Europe**
- **Dermira to receive an option fee of \$30 MM**
- **Lebrikizumab is an investigational anti-IL-13 monoclonal antibody currently in Phase 2b development with topline data expected by early April 2019**

[Almirall, S.A.](#) (ALM) and Dermira, Inc. (NASDAQ: DERM) announced today that the companies have entered into an option and license agreement under which Almirall has acquired an option to exclusively license rights to develop and commercialize lebrikizumab for the treatment of atopic dermatitis and certain other indications in Europe. In exchange, Dermira will receive an upfront option fee of \$30 MM.

If Almirall exercises its option to obtain the license following the results of the ongoing Phase 2b study, Dermira will receive a \$50 MM option exercise fee and will be eligible to receive additional development, regulatory and sales milestone payments, as well as double-digit royalties.

Lebrikizumab is an investigational monoclonal antibody that blocks signaling of IL-13, a cytokine that plays a key role in the pathogenesis of moderate-to-severe atopic dermatitis. Based on the central role of IL-13 in atopic dermatitis and lebrikizumab's unique molecular profile, combining a differentiated mechanism of action, high affinity for its target and robust pharmacokinetics, Dermira and Almirall believe targeting IL-13 with lebrikizumab presents an opportunity to deliver a therapy with a compelling combination of safety, tolerability, efficacy, convenience and ease of use to people living with moderate-to-severe atopic dermatitis and the healthcare practitioners who care for them.

"As a prevalent, debilitating condition with limited treatment options, moderate-to-severe atopic dermatitis represents a significant unmet medical need. Almirall shares our commitment to dermatology and excitement about the opportunity for lebrikizumab to advance the standard of care for the millions of people living this condition," said Tom Wiggins, Chairman and Chief Executive Officer of Dermira. *"This transaction is an excellent financial, operational and strategic fit for Dermira, and we are pleased to have the opportunity to enlist Almirall's development and commercial expertise to help make lebrikizumab available in Europe while we continue to pursue development and potential commercialization in the U.S."*

Under the terms of the agreement, Almirall will make an initial payment of \$30 MM to Dermira in exchange for an option to acquire an exclusive license to develop lebrikizumab in dermatology indications and commercialize lebrikizumab in all indications in Europe. Following the availability of topline data from Dermira's ongoing Phase 2b clinical study of lebrikizumab in moderate-to-severe atopic dermatitis, Dermira will provide to Almirall a data

package consisting of topline and additional data, after which Almirall will have 45 days to exercise its option. If Almirall elects to exercise its option, the company will pay Dermira an option exercise fee of \$50 MM.

If Almirall exercises its option, Almirall will be obligated to make additional payments to Dermira upon the achievement of certain milestones, including \$30 MM in connection with the initiation of certain Phase 3 clinical studies and up to \$85 MM upon the achievement of regulatory milestones and the first commercial sale of lebrikizumab in Europe. In addition, Dermira will be entitled to receive milestone payments upon the achievement of certain thresholds for net sales of lebrikizumab in Europe, as well as royalty payments representing percentages of net sales that range from the low double-digits to the low twenties.

“At Almirall, we continue to deepen in our commitment to dermatology,” said Peter Guenter, Chief Executive Officer of Almirall. *“Atopic dermatitis is a condition that affects millions of people living in Europe, and we are pleased to support the development and commercialization of lebrikizumab, a differentiated treatment that we believe could become a best-in-disease therapy for these patients. We are excited to be collaborating with Dermira and look forward to positive results from the Phase 2b study and subsequently moving into registrational studies.”*

Lebrikizumab Phase 2b Study Design

Dermira is conducting a randomized, double-blind, placebo-controlled, parallel-group Phase 2b study evaluating the safety and efficacy of lebrikizumab as monotherapy in patients with moderate-to-severe atopic dermatitis. Based on early clinical experience with lebrikizumab, the study is designed to build on the body of evidence supporting targeting of IL-13 in atopic dermatitis by evaluating three different dosing regimens, with the objective of optimizing the clinical profile of lebrikizumab and establishing the dosing regimen for a potential Phase 3 program. The study enrolled 280 patients ages 18 years and older with moderate-to-severe atopic dermatitis in the United States, randomized in a 3:3:3:2 fashion as follows:

- **Group 1:** A loading dose of 250 mg of lebrikizumab at week 0, followed by 125 mg of lebrikizumab every four weeks.
- **Group 2:** A loading dose of 500 mg of lebrikizumab at week 0, followed by 250 mg of lebrikizumab every four weeks.
- **Group 3:** A loading dose of 500 mg of lebrikizumab at each of weeks 0 and 2, followed by 250 mg of lebrikizumab every two weeks.
- **Group 4:** Placebo at week 0 and every two weeks thereafter.

The primary endpoint of the study is the percent change in the Eczema Area Severity Index (EASI) from baseline to week 16. Key secondary endpoints that will be evaluated during the 16-week treatment period include: the proportion of patients with a 75 percent improvement from baseline in EASI (EASI-75); the proportion of patients with an Investigator’s Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and a reduction of 2 or more points (on a 5-point scale) from baseline; the proportion of patients achieving EASI-50 and EASI-90; and changes in pruritus (itch) and sleep loss scores from baseline, both scored using an 11-point numerical rating scale (NRS). Key inclusion criteria for patients enrolled in this study included chronic atopic dermatitis for at least one year, an EASI score of 16 or greater, an IGA score of 3 or greater, and a body surface area involving at least 10 percent at screening and baseline. Following the end of the 16-week assessment period, patients will be followed for an additional 16 weeks. Topline safety and efficacy results from the study are expected by early April 2019.

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 persistent itching and red, dry, cracked skin that covers much of the body. The skin 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, humanized monoclonal antibody designed to bind IL-13 with 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 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 Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed. The company, founded 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 major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenues in 2017 were 755.8 million euros. It has more than 1,830 employees.

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

About Dermira

Dermira is a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. Dermira is committed to understanding the needs of both patients and physicians and using its insight to identify, develop and commercialize leading-edge medical dermatology products. The company's approved treatment, QBREXZA™ (glycopyrronium) cloth, is indicated for pediatric and adult patients (ages nine and older) with primary axillary hyperhidrosis (excessive underarm sweating). Dermira is also evaluating lebrikizumab in a Phase 2b clinical trial for the treatment of moderate-to-severe atopic dermatitis (a severe form of eczema) and has early-stage research programs in other areas of dermatology. Dermira is headquartered in Menlo Park, Calif. For more information, please visit <http://www.dermira.com>. Follow Dermira on [LinkedIn](#), [Instagram](#) and [Twitter](#).

In addition to filings with the Securities and Exchange Commission (SEC), press releases, public conference calls and webcasts, Dermira uses its website (www.dermira.com), LinkedIn page (<https://www.linkedin.com/company/dermira-inc->), corporate Instagram account (https://www.instagram.com/dermira_inc/) and corporate Twitter account (@DermiraInc) as channels of distribution of information about its company, product candidates, planned financial and other announcements, attendance at upcoming investor and industry conferences and other matters. Such information may be deemed material information and Dermira may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Dermira's website, LinkedIn page, Instagram and Twitter accounts in addition to following its SEC filings, news releases, public conference calls and webcasts.

Forward-Looking Statements

The information in this news release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. This news release contains forward-looking statements that involve substantial risks and uncertainties, including statements with respect to: Dermira’s goal of bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions; the opportunity to deliver a product having a combination of safety, tolerability, efficacy, convenience and ease of use to people living with moderate-to-severe atopic dermatitis and the healthcare practitioners who care for them; the hope that lebrikizumab will advance the standard of care for the millions of people living with atopic dermatitis; the belief that lebrikizumab could become a best-in-disease therapy for the treatment of moderate-to-severe atopic dermatitis; the successful completion of, and timing expectations for the receipt and announcement of topline data from, the Phase 2b study of lebrikizumab for the treatment of moderate-to-severe atopic dermatitis; the potential exercise of the option by Almirall and the anticipated fees, payments and royalties associated therewith; future registrational studies of lebrikizumab in patients with moderate-to-severe atopic dermatitis; potential regulatory approval and the future availability of lebrikizumab for the treatment of moderate-to-severe atopic dermatitis; and the anticipated creation of a growth platform for Dermira and Almirall. These statements deal with future events and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to the design, implementation and outcomes of current and future clinical trials; dependence on third-party clinical research organizations, manufacturers, suppliers and distributors; the outcomes of future meetings with regulatory agencies; Dermira’s ability to develop and maintain collaborations and license products and intellectual property; Dermira’s ability to attract and retain key employees; Dermira’s ability to obtain necessary additional capital; market acceptance of Dermira’s potential products; the impact of competitive products and therapies; Dermira’s ability to manage the growth and complexity of its organization; Dermira’s ability to maintain, protect and enhance its intellectual property; and Dermira’s ability to continue to stay in compliance with applicable laws and regulations. You should refer to the section entitled “Risk Factors” set forth in Dermira’s Annual Report on Form 10-K, Dermira’s Quarterly Reports on Form 10-Q and other filings Dermira makes with the SEC from time to time for a discussion of important factors that may cause actual results to differ materially from those expressed or implied by Dermira’s forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this news release. Dermira undertakes no obligation to publicly update any forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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