More than two-thirds of people with atopic dermatitis and skin of color experienced skin improvement in a first-of-its-kind lebrikizumab study

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INDIANAPOLIS, March 10, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced results from a first-of-its-kind study of lebrikizumab specifically designed for people with skin of color and moderate-to-severe atopic dermatitis, commonly called eczema. In this study, treatment with lebrikizumab, an investigational medicine, showed improvement in skin clearance and itch relief. These late-breaking results from a Phase 3 study are being presented today at the American Academy of Dermatology (AAD) Annual Meeting.

The lebrikizumab efficacy results from this trial are consistent with data in other Phase 3 studies, which further reinforces lebrikizumab's potential to be a first-line biologic treatment following topical prescription therapies for people across a range of skin tones with moderate-to-severe atopic dermatitis.

"People with skin of color are disproportionately affected by atopic dermatitis, often experiencing more severe symptoms, a delay in diagnosis and a lengthier timeframe to find appropriate treatment. They also have been historically underrepresented in clinical trials, which means we have lacked data pertaining to the treatment of patients with skin of color," said Andrew Alexis, M.D., M.P.H., Professor of Clinical Dermatology and Vice Chair for Diversity and Inclusion in the Department of Dermatology at Weill Cornell Medicine, a dermatologist at New York-Presbyterian/Weill Cornell Medical Center, and lead study investigator. "With these initial results, Lilly is taking a step toward investigating the needs of people with skin of color affected by atopic dermatitis."

The initial 16-week data from this study evaluated 50 patients with moderate-to-severe atopic dermatitis and darker skin tones as measured by the Fitzpatrick scale[¶], including people who self-identify as Black or African American (80%), Asian (14%), American Indian or Alaska Native (6%). Of the 50 patients, 11 also self-identified as Hispanic/Latinx (22%) with the remaining 39 self-identifying as non-Hispanic/Latinx (78%). All patients received lebrikizumab 500-mg subcutaneously initially and at two weeks followed by 250-mg subcutaneously every two weeks to Week 16. Results at 16 weeks were consistent with the 16-week results from the ADhere and ADvocate 1 & 2 studies.

- 68% of people experienced significant improvement of at least 75% in disease extent and severity (EASI-75)[*].
- 46% of people experienced at least 90% improvement in disease extent and severity (EASI-90)[†].
- 39% of people achieved clear or almost clear skin (IGA 0,1)[‡] with a reduction of at least two points from baseline.
- 56% of people experienced clinically meaningful itch relief (PNRS ≥4-point improvement)[§].

No new safety signals were observed and there were no serious adverse events reported. The study also included a physician assessment of changes in post-inflammatory pigmentation using the newly developed PDCA-Derm™ scale. Full efficacy and safety results from the study will be shared at future congresses.

"Lebrikizumab is the first investigative treatment for atopic dermatitis to disclose robust efficacy data specifically for people with skin of color, who may experience barriers to treatment or inequitable care," said Mark Genovese, M.D., senior vice president of Immunology Development at Lilly. "Through clinical trials like this, we hope to deliver more breakthroughs to make life better for people who have been underserved."

Lilly is committed to finding solutions to elevate care and improve treatment outcomes for all people living with dermatologic conditions, including addressing the unmet needs of people with skin of color. The company's work to advance health equity in dermatology is focused on engaging in impactful research that improves patient care, supporting health care providers with education to increase awareness of dermatologic diseases in patients with skin of color, and empowering the patient voice so patients can make their needs known and actively partner to find meaningful solutions.

Specific to clinical research, Lilly continues to engage in efforts to involve a more diverse range of participants in clinical trials and establish clear, measurable goals to drive progress.

Lilly has exclusive rights for development and commercialization of lebrikizumab in the U.S. and the rest of the world outside Europe. Lilly's partner Almirall S.A. has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including eczema, in Europe.

*EASI=Eczema Area and Severity Index, EASI-75=75 percent reduction in EASI from baseline to Week 16
† Eczema Area and Severity Index ≥ 90 percent Reduction
‡ IGA=Investigator's Global Assessment 0 or 1 ("clear" or "almost clear")
§ PNRS=Pruritus Numeric Rating Scale in participants with a baseline PNRS of ≥ 4
¶ Fitzpatrick phototype describes the amount of melanin pigment in the skin by determining constitutional color and the effect of exposure to ultraviolet radiation and "darker skin tone" is defined as IV-VI on the scale

About ADmirable

ADmirable (NCT05372419)[1] is a Phase 3b, open-label, 24-week study, evaluating the safety and efficacy of lebrikizumab in adult and adolescent patients with skin of color and moderate-to-severe atopic dermatitis and defining innovative objective measures of pigment, erythema, and post-inflammatory hyper and hypopigmentation. Patients enrolled in the ADmirable study received lebrikizumab 500-mg subcutaneously initially and at two weeks followed by 250-mg every two weeks until Week 16.[2] These interim data, which were analyzed before the completion of the 24-week study, represent primary and secondary endpoints from the study at 16 weeks.

About Lebrikizumab and Clinical Development Program
Lebrikizumab is an investigational, monoclonal antibody that targets IL-13 with high binding affinity and slow dissociation rate, to specifically prevent the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13.[3-5] The cytokine IL-13 is key in atopic dermatitis, driving the type-2 inflammatory loop in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.[6,7]

The lebrikizumab Phase 3 program consists of five key global studies evaluating over 1,300 patients, including two monotherapy studies (ADvocate 1 and 2), a combination study with topical corticosteroids (ADhere), as well as long-term extension (ADjoin) and adolescent open label (ADore) studies. Further data results from a study dedicated to people with skin of color (ADmirable) and patients previously treated with dupilumab (ADapt) are expected to be shared in late 2024.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram and LinkedIn.

*Disclosure: Dr. Andrew Alexis is a paid advisory member and speaker for Eli Lilly and Company. He has not been compensated for any media work.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about lebrikizumab as a treatment for people with moderate-to-severe atopic dermatitis and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, or that lebrikizumab will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

[1] Alexis A, et al. presented at Maui Derm 2024.

[2] Alexis A, et al. Efficacy and safety of lebrikizumab in adult and adolescent patients with skin of color and moderate-to-severe atopic dermatitis: an interim analysis of the open-label phase 3b trial, ADmirable. 2024 American Academy of Dermatology Conference. March 10, 2024.

[3] Simpson EL, et al. Efficacy and safety of lebrikizumab (an anti-IL-13 monoclonal antibody) in adults with moderate-to-severe atopic dermatitis inadequately controlled by topical corticosteroids: A randomized, placebo-controlled phase II trial (TREBLE). J Am Acad Dermatol. 2018;78(5):863-871.e11. doi:10.1016/j.jaad.2018.01.017

[4] Okragly A, et al. Binding, Neutralization and Internalization of the Interleukin-13 Antibody, Lebrikizumab. Dermatol Ther (Heidelb). 2023;13(7):1535-1547. doi:10.1007/s13555-023-00947-7

[5] Ultsch M, et al. Structural basis of signaling blockade by anti-IL-13 antibody Lebrikizumab. J Mol Biol. 2013;425(8):1330-1339. doi:10.1016/j.jmb.2013.01.024

[6] Bieber T. Interleukin-13: Targeting an underestimated cytokine in atopic dermatitis. Allergy. 2020;75(1):54–62. doi:10.1111/all.13954

[7] Tsoi LC, et al. Atopic Dermatitis Is an IL-13-Dominant Disease with Greater Molecular Heterogeneity Compared to Psoriasis. J Invest Dermatol. 2019;139(7):1480-1489. doi:10.1016/j.jid.2018.12.018

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