



Nearly 80% of patients with moderate-to-severe atopic dermatitis maintained clear or almost clear skin with Lilly's lebrikizumab monthly maintenance dosing at two years

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First readout of two-year data from long-term extension study

INDIANAPOLIS, Oct. 20, 2023 /PRNewswire/ -- Patients with moderate-to-severe atopic dermatitis who continued treatment with investigational lebrikizumab for up to two years experienced sustained skin clearance, itch relief and reduced disease severity with monthly maintenance dosing as demonstrated in the ADjoin long-term extension study from Eli Lilly and Company (NYSE: LLY). Results from ADjoin will be presented at the 43rd Annual Fall Clinical Dermatology Conference happening from October 19-22 in Las Vegas, Nevada.¹

"Lebrikizumab, administered with a once-monthly dose following an induction phase, demonstrated efficacy for patients with moderate-to-severe atopic dermatitis, offering sustained relief from some of the most distressing signs and symptoms of the disease," said Emma Guttman-Yassky, M.D., Ph.D., The Waldman Professor and Health System Chair, Department of Dermatology, Director, Center of Excellence in Eczema and the Laboratory for Inflammatory Skin Diseases at the Icahn School of Medicine at Mount Sinai in New York, and senior author and investigator of the ADjoin analysis. "Long-term data is critical for healthcare providers making treatment decisions with patients. These impressive two-year data underscore the lasting impact this potential first-line biologic treatment option may provide for people living with this disruptive disease."

Lebrikizumab is an interleukin-13 (IL-13) inhibitor that specifically blocks IL-13 signaling.^{2,3,4} 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.^{5,6}

ADjoin is the two-year extension of the lebrikizumab monotherapy trials ADvocate 1 and ADvocate 2 and ADhere, the combination trial with topical corticosteroids. Patients taking lebrikizumab who achieved IGA 0,1 or EASI-75 at 16 weeks in ADvocate 1 and 2 and ADhere were enrolled in ADjoin. Patients in the long-term extension trial received either lebrikizumab 250-mg every two weeks or monthly.¹

In ADjoin, lebrikizumab provided durable efficacy in skin and itch outcomes through two years of treatment with both monthly and two-week dosing.¹

Efficacy Outcomes of Patients Entering Long-Term Extension Trial ADjoin				
Outcome, %	ADvocate 1&2 → ADjoin		ADhere → ADjoin	
	Monthly (Q4W) LEBRI 250 mg (N=99)	Every two weeks (Q2W) LEBRI 250 mg (N=82)	Monthly (Q4W) LEBRI 250 mg (N=29)	Every two weeks (Q2W) LEBRI 250 mg (N=57)
IGA (0,1)	76	86	79	84
EASI 75	96	96	96	95
EASI 90	83	82	72	85
Pruritus NRS (Itch) ≥ 4-point improvement	90	100	90*	82*

* Data through 68 weeks for Pruritus NRS ≥4-point improvement for ADhere → ADjoin study; data through 104 weeks for all other outcomes

EASI=Eczema Area and Severity Index; EASI 75=at least 75% improvement from baseline in EASI; EASI 90=at least 90% improvement from baseline in EASI; IGA=Investigator's Global Assessment; IGA (0,1)=IGA response of clear or almost clear; NRS=numeric rating scale; Q2W=every 2 weeks; Q4W=every 4 weeks (monthly)

The safety profile of lebrikizumab in ADjoin was consistent with previous lebrikizumab studies in patients with moderate-to-severe atopic dermatitis, and no new safety signals were observed up to two years of treatment. In ADjoin, 62 percent of patients reported adverse events (AEs), most of which were mild or moderate in severity. The most common side effects of lebrikizumab were conjunctivitis, injection site reactions and shingles (herpes zoster). Less than three percent of patients experienced AEs leading to treatment discontinuation.¹

"Results from ADjoin reinforce the strong efficacy and safety profile of lebrikizumab seen in the other Phase 3 atopic dermatitis trials. These data also further our understanding of the long-lasting benefits of lebrikizumab as a potential first-line biologic treatment for patients," said Lotus Mallbris, M.D., Ph.D., senior vice president of global immunology development and medical affairs at Lilly. "We look forward to working with global regulatory authorities to bring this important medicine to patients."

The two-year long-term extension data build on the positive one-year results from the monotherapy studies previously published in [British Journal of Dermatology](#) as well as the 16-week monotherapy data published in [The New England Journal of Medicine](#). An additional 18 abstracts related to the lebrikizumab development program are being presented at the Fall Clinical Dermatology Conference that further explore key topics affecting patients with atopic dermatitis including key learnings from an exploratory analysis on lebrikizumab speed of response, itch-free days and stability of itch.

"The two-year data from the ADjoin study further validate the promising efficacy and safety profile of lebrikizumab in people with moderate-to-severe

atopic dermatitis. These results demonstrated that monthly maintenance dosing of lebrikizumab provided long-lasting relief from the distressing symptoms of this chronic disease, bringing us one step closer to offering a first-line biologic treatment option," stated Karl Ziegelbauer, Ph.D., Chief Scientific Officer at Almirall S.A.

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 has licensed the rights to develop and commercialize lebrikizumab for the treatment of dermatology indications, including eczema, in Europe.

About ADjoin

ADjoin ([NCT04392154](#)) evaluated the efficacy and safety of lebrikizumab treatment for two years. Patients taking lebrikizumab who achieved IGA 0,1 or EASI-75 at 16 weeks in ADvocate 1 and 2 and ADhere were enrolled in ADjoin. Patients in the long-term extension trial received either lebrikizumab 250-mg every two weeks or monthly.¹

About lebrikizumab and Clinical Development Program

Lebrikizumab is an investigational, monoclonal antibody that binds IL-13 to specifically prevent the formation of the IL-13R α 1/IL-4R α heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13.²⁻⁴ 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.^{5,6}

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. Lilly has also initiated an innovative [clinical study](#) dedicated to people of color living with atopic dermatitis. The study will further evaluate the efficacy and safety of lebrikizumab in people of color to generate additional data and disease information to help investigators and clinicians provide better diagnoses and treatment options.

About Lilly

Lilly unites caring with discovery to create medicines that 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](#), [Twitter](#) and [LinkedIn](#). P-LLY

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 potential 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 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 Guttman-Yassky E, et al. Efficacy and Safety of Lebrikizumab Is Maintained to Two Years in Patients With Moderate-to-Severe Atopic Dermatitis. 2023 Fall Clinical Dermatology Conference. October 20, 2023.

² 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

³ 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

⁴ 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

⁵ Bieber T. Interleukin-13: Targeting an underestimated cytokine in atopic dermatitis. *Allergy*. 2020;75(1):54-62. doi:10.1111/all.13954

⁶ 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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