Lilly's EBGLYSS (lebrikizumab-lbkz) delivered durable disease control when administered once every eight weeks in patients with moderate-to-severe atopic dermatitis

October 24, 2025

New long-term extension data show approximately 80% of patients achieved or maintained meaningful skin improvement (EASI 75) with EBGLYSS with half the doses compared to approved monthly maintenance dosing

Lilly submitted these data to the FDA for a potential label update for EBGLYSS

If approved, EBGLYSS would be a first-line biologic that offers the option of monotherapy with once every eight-week maintenance dosing in moderate-to-severe atopic dermatitis uncontrolled by topicals

INDIANAPOLIS, Oct. 24, 2025 /PRNewswire/ -- New results show Eli Lilly and Company's (NYSE: LLY) EBGLYSS (lebrikizumab-lbkz) sustained similar levels of skin clearance when administered as a single injection of 250 mg once every eight weeks (Q8W) compared with once every four weeks (Q4W), supporting a potential additional, less frequent maintenance dosing option for more individualized treatment of patients with moderate-to-severe atopic dermatitis. These findings from the Phase 3 ADjoin extension trial will be presented at the 2025 Fall Clinical Dermatology Conference, taking place Oct. 23-26 in Las Vegas.[1]

"For people managing the persistent symptoms of eczema, hesitancy about frequent injections can add to the already heavy toll of this disease," said Peter Lio, M.D., author of the ADjoin study and clinical assistant professor of dermatology and pediatrics, Northwestern University. "With as few as six maintenance doses per year, EBGLYSS would give patients and providers more flexibility, which may reduce treatment burden for patients with busy lives."

EBGLYSS is an interleukin-13 (IL-13) inhibitor that selectively blocks IL-13 signaling with high binding affinity.[2,3,4] The cytokine IL-13 is a primary cytokine in atopic dermatitis, driving the type-2 inflammatory cycle in the skin, leading to skin barrier dysfunction, itch, skin thickening and infection.[5,6]

In the ADjoin extension study, results indicate that maintenance dosing every other month demonstrated similarly high rates of disease control compared to monthly dosing:

- 79% of patients taking EBGLYSS once every other month and 86% of patients taking EBGLYSS monthly, respectively, achieved or maintained EASI 75.*
- 62% of patients taking EBGLYSS once every other month and 73% of patients taking EBGLYSS monthly, respectively, achieved or maintained IGA 0,1.
- There was no increased risk of immunogenicity (the production of anti-drug-antibodies), and no new safety findings. These data support that once every eight-week EBGLYSS dosing could give HCPs and patients a new treatment option using the lowest effective dose.

"Managing moderate-to-severe atopic dermatitis involves ongoing cycles of flare-ups and itching, which can be difficult for people with eczema," said Kristin Belleson, President and CEO of the National Eczema Association. "Treatment options that have the potential to reduce the time people spend managing symptoms could give them more time to focus on what matters most."

Lilly has submitted these data from the ADjoin extension trial among other data to the FDA for a potential label update. A study investigating EBGLYSS maintenance dosing of 500 mg administered once every 12 weeks (Q12W) is underway.

"Lilly continues to optimize dosing frequency to push boundaries that redefine the patient experience. These new findings build on EBGLYSS' proven efficacy and demonstrate the potential for disease control with even less frequent dosing," said Mark Genovese M.D., senior vice president of Lilly Immunology development. "We are pursuing an every-eight-week maintenance dosing label update with the FDA. We are also testing every-twelve-week maintenance dosing with our partner Almirall, as well as potentially exploring every-twelve-week dosing in independent Lilly-led studies."

These data build on existing research for EBGLYSS, which has demonstrated long-term results maintained for up to three years, as well as efficacy data across diverse skin tones. EBGLYSS is the only biologic for moderate-to-severe atopic dermatitis with a strong recommendation and high certainty of evidence that can be used with or without topicals, according to guidelines published by the American Academy of Dermatology (AAD),** which are used as a key consideration for dermatologists and managed care providers.

Lilly continues to raise the standard of care in dermatology and invest in our immunology pipeline, which includes big bets on next-generation modalities and the targeted expansion of small molecules. Lilly's investigational therapies include novel, oral IL-17 inhibitors such as DICE Therapeutics' DC-853, which is being studied for psoriasis, and eltrekibart, a novel monoclonal antibody that targets neutrophil-driven inflammation and is being assessed in hidradenitis suppurativa. Lilly is also advancing novel science to explore the potential of incretins in dermatology and has initiated the TOGETHER-PsO trial investigating the efficacy and safety of treating adults with moderate-to-severe plaque psoriasis and obesity with both ixekizumab and an incretin-based therapy.

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

*EASI=Eczema Area and Severity Index, EASI-75=75% reduction in EASI from baseline; IGA=Investigator's Global Assessment 0 or 1 ("clear" or "almost clear").
**Inclusion in the *Focused Update: AAD Guidelines of Care for the Management of Atopic Dermatitis in Adults* does not denote endorsement of product use by the AAD.

About the Q8W ADjoin Extension
The Q8W extension of ADjoin (NCT04392154) assessed EBGLYSS given every eight weeks (Q8W) compared to every four weeks (Q4W) and evaluated the long-term safety and efficacy of EBGLYSS treatment in patients with moderate-to-severe atopic dermatitis for 32 weeks, in select countries. Adult and adolescent patients (ages 12–17, weighing ≥40 kg) who completed the 100-week ADjoin study, including participants from the ADvocate 1 and 2 trials (52 weeks), ADore trial (52 weeks) and the ADopt-VA (16 weeks) trial, were eligible to enroll in the Q8W extension. Patients in this analysis received open-label EBGLYSS 250 mg, Q8W or Q4W, regardless of their previous treatment in ADjoin (Q2W or Q4W dose). The approved maintenance dose of EBGLYSS is 250 mg once monthly, after taking EBGLYSS 250 mg every two weeks for 16 weeks or later when adequate clinical response is achieved.[7]

INDICATION AND SAFETY SUMMARY
EBGLYSS™ (EHB-glihs) is an injectable medicine used to treat adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) with moderate-to-severe eczema (atopic dermatitis) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. EBGLYSS can be used with or without topical corticosteroids.

It is not known if EBGLYSS is safe and effective in children less than 12 years of age or in children 12 years to less than 18 years of age who weigh less than 88 pounds (40 kg).

Warnings - Do not use EBGLYSS if you are allergic to lebrikizumab-lbkz or to any of the ingredients in EBGLYSS. See the Patient Information leaflet that comes with EBGLYSS for a complete list of ingredients.

Before using
Before using EBGLYSS, tell your healthcare provider about all your medical conditions, including if you:

- Have a parasitic (helminth) infection.
- Are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with EBGLYSS.
- Are pregnant or plan to become pregnant. It is not known if EBGLYSS will harm your unborn baby. If you become pregnant during treatment with EBGLYSS, you or your healthcare provider can call Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) to report the pregnancy.
- Are breastfeeding or plan to breastfeed. It is not known if EBGLYSS passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Possible side effects
EBGLYSS can cause serious side effects, including:

- **Allergic reactions. EBGLYSS can cause allergic reactions that may sometimes be severe.** Stop using EBGLYSS and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms:
  - breathing problems or wheezing
  - swelling of the face, lips, mouth, tongue or throat
  - hives
  - itching
  - fainting, dizziness, feeling lightheaded
  - skin rash
  - cramps in your stomach area (abdomen)
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision.

The most common side effects of EBGLYSS include:

- eye and eyelid inflammation, including redness, swelling, and itching
- injection site reactions
- shingles (herpes zoster)

These are not all of the possible side effects of EBGLYSS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

How to take

- **See the detailed "Instructions for Use" that comes with EBGLYSS for information about how to prepare and inject EBGLYSS and how to properly store and throw away (dispose of) used EBGLYSS prefilled pens and prefilled syringes.**
- Use EBGLYSS exactly as prescribed by your healthcare provider.
- EBGLYSS is given as an injection under the skin (subcutaneous injection).

- If your healthcare provider decides that you or a caregiver can give the injections of EBGLYSS, you or a caregiver should receive training on the right way to prepare and inject EBGLYSS. Do not try to inject EBGLYSS until you have been shown the right way by your healthcare provider. In children 12 years of age and older, EBGLYSS should be given by a caregiver.
- If you miss a dose of EBGLYSS, inject the missed dose as soon as possible, then inject your next dose at your regular scheduled time.

Learn more
EBGLYSS is a prescription medicine available as a 250 mg/2 mL injection prefilled pen or prefilled syringe. For more information, call **1-800-545-5979** or go to **ebglyss.lilly.com**

This summary provides basic information about EBGLYSS but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking to your doctor. Be sure to talk to your doctor or other healthcare provider about EBGLYSS and how to take it. Your doctor is the best person to help you decide if EBGLYSS is right for you.

LK CON BS AD APP

EBGLYSS, its delivery device base, and Lilly Support Services are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

About EBGLYSS
EBGLYSS is a monoclonal antibody that selectively targets and neutralizes IL-13 with high binding affinity and a slow dissociation rate.[3,4,7] EBGLYSS binds to the IL-13 cytokine at an area that overlaps with the binding site of the IL-4Rα subunit of the IL-13Rα1/IL-4Rα heterodimer, preventing formation of this receptor complex and inhibiting IL-13 signaling. IL-13 is implicated as a primary cytokine tied to the pathophysiology of eczema, driving the type-2 inflammatory loop in the skin, and EBGLYSS selectively targets IL-13.[7]

The EBGLYSS 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.

EBGLYSS was approved in the U.S. by the Food and Drug Administration (FDA) in 2024 as a first-line monotherapy biologic treatment with once-monthly maintenance dosing for adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) with moderate-to-severe atopic dermatitis that is not well controlled with topical prescription therapies.[7] EBGLYSS was also approved in the European Union in 2023 and in Japan and Canada in 2024.

EBGLYSS 250 mg/2 mL injection is dosed as a single monthly maintenance injection following the initial phase of treatment. The recommended initial starting dose of EBGLYSS is 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg every two weeks until Week 16 or later when adequate clinical response is achieved; after this, maintenance dosing is a single monthly injection (250 mg every four weeks).[7]

Lilly is committed to serving patients living with moderate-to-severe atopic dermatitis and is working to enable broad first-line biologic access to EBGLYSS following topical prescription therapy through commercial insurance and as of October 24, Lilly has coverage with all three major national pharmacy benefit managers and over 90% of people with commercial insurance. We are also pursuing similarly broad Medicaid and Medicare coverage as part of Lilly's health access and affordability initiative. Through Lilly Support Services, Lilly offers a patient support program including co-pay assistance for eligible, commercially insured patients.

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 tens of millions of 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. P-LLY

Trademarks and Trade Names
All trademarks or trade names referred to in this press release are the property of the company, or, to the extent trademarks or trade names belonging to other companies are references in this press release, the property of their respective owners. Solely for convenience, the trademarks and trade names in this press release are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the company or, to the extent applicable, their respective owners will not assert, to the fullest extent under applicable law, the company's or their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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 EBGLYSS (lebrikizumab-lbkz) as a treatment for patients with moderate-to severe atopic dermatitis and the timeline for future readouts, presentations, and other milestones relating to EBGLYSS and its clinical trials 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 future study results will be consistent with the results to date or that EBGLYSS will receive additional regulatory approvals, or that it will 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. Silverberg J, et al. Lebrikizumab Dosed Every 8 Weeks as Maintenance Provides Long-Lasting Response in Patients with

Moderate-to-Severe Atopic Dermatitis. 2025 Fall Clinical Dermatology Conference. October 24, 2025.
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:10.10116/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.
7. EBGLYSS. Prescribing Information. Lilly USA, LLC.

Refer to: Julia Brennan; julia.brennan@lilly.com; 463-245-3586 (Lilly media)
Michael Czapar; czapar_michael_c@lilly.com; 317-617-0983 (Investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/lillys-ebglyss-lebrikizumab-lbkz-delivered-durable-disease-control-when-administered-once-every-eight-weeks-in-patients-with-moderate-to-severe-atopic-dermatitis-302593427.html

SOURCE Eli Lilly and Company