FDA approves Lilly's EBGLYSS® (lebrikizumab-lbkz) for one maintenance dose every eight weeks in patients with moderate-to-severe atopic dermatitis

June 9, 2026

EBGLYSS is now the only approved option that offers as few as six maintenance injections per year with no required topicals from the start

INDIANAPOLIS, June 9, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) approved a regimen of one maintenance dose every eight weeks of a single injection (250 mg/2 mL) of EBGLYSS (lebrikizumab-lbkz) for subcutaneous use in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) with moderate-to-severe atopic dermatitis. EBGLYSS is already approved for a once-monthly maintenance dose, with long-term data showing durable disease control. Now, EBGLYSS gives patients with moderate-to-severe atopic dermatitis the option to manage their condition with as few as six maintenance injections per year.[1]

"Today's approval builds on EBGLYSS' established long-term durability, with a new option for one maintenance dose every eight weeks. For people living with moderate-to-severe atopic dermatitis, that means a treatment they only need to take as few as six times a year—without prescription topicals from the start," said Adrienne Brown, executive vice president and president of Lilly Immunology. "EBGLYSS now gives patients the opportunity to flare less and live their lives with fewer interruptions from atopic dermatitis."

The approval is based on longitudinal exposure-response modeling data and supported by every-eight-week clinical data from an extension to the Phase 3 ADjoin long-term trial, which evaluated EBGLYSS maintenance dosing every four weeks or every eight weeks over 32 weeks.[2]

"The option to extend EBGLYSS maintenance dosing to every eight weeks represents an important moment for patients living with moderate-to-severe atopic dermatitis," said Peter Lio, M.D., author of the ADjoin study and clinical assistant professor of dermatology and pediatrics, Northwestern University. "This new dosing regimen without mandatory topicals gives patients a new option to manage their condition based on individual needs. It's about meeting patients where they are in their lives."

No new safety signals were noted in the EBGLYSS safety data in the 32-week ADjoin Q8W extension. No patients discontinued due to adverse events through 32 weeks. The most common (≥1%) adverse reactions reported with EBGLYSS are conjunctivitis, injection site reactions and herpes zoster.[1]

"Living with moderate-to-severe atopic dermatitis often means dealing with a cycle of symptoms and time-intensive treatment routines during and in-between flares," said Kristin Belleson, president and CEO of the National Eczema Association. "Patients living with moderate-to-severe atopic dermatitis seek treatments that can offer durable disease control and fewer injections. This new option can ease the burden, allowing patients to spend less time thinking about managing their condition on a daily basis."

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

About the Q8W ADjoin Extension
The Q8W ADjoin extension (NCT04392154) evaluated EBGLYSS administered once every eight weeks (Q8W) and once every four weeks (Q4W), assessing its long-term safety and efficacy over 32 weeks in patients with moderate-to-severe atopic dermatitis across select countries. Adult and adolescent patients (ages 12–17, weighing ≥40 kg) who completed the 100-week ADjoin long-term study, including participants from the Phase 3 ADvocate 1 and 2 trials (52 weeks), ADore trial (52 weeks) and the ADopt-VA (16 weeks) trial, were eligible to enroll. Patients in this analysis received open-label EBGLYSS 250 mg, Q8W or Q4W, regardless of their previous treatment in ADjoin (Q2W or Q4W dose) or response at extension baseline. The approved maintenance dose of EBGLYSS is 250 mg every four weeks or 250 mg every eight weeks, after taking EBGLYSS 250 mg every two weeks for 16 weeks or later when adequate clinical response is achieved.

About EBGLYSS
EBGLYSS is a monoclonal antibody that selectively targets and neutralizes IL-13 with high binding affinity and a slow dissociation rate.[1,3,4] 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 atopic dermatitis, driving the type-2 inflammatory loop in the skin, and EBGLYSS selectively targets IL-13.[1]

The EBGLYSS Phase 3 program in atopic dermatitis consists of seven key global studies evaluating more than 1,600 patients, including two monotherapy studies (ADvocate 1 and 2), a combination study with topical corticosteroids (ADhere), long-term extension (ADjoin) and adolescent open-label (ADore) studies. The program also includes a study assessing the impact of EBGLYSS on vaccine immune response in adults (ADopt-VA). EBGLYSS has been studied in patients with skin of color (ADmirable) and in dupilumab-experienced patients (ADapt).

EBGLYSS was approved in the U.S., Japan and Canada in 2024 and in the European Union in 2023. EBGLYSS is a first-line biologic treatment, administered with or without topical corticosteroids, that offers every-four-week or every-eight-week 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.[1] In the U.S., 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 250 mg every four weeks or every eight weeks.[1]

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 for patients not well-controlled with topical prescription therapy through commercial insurance. Lilly has coverage with all three major

national pharmacy benefit managers and 94% of commercially insured patients have coverage through national health plans. We have expanded Medicaid coverage and are pursuing similarly broad Medicare coverage as part of Lilly's health equity and affordability initiative. Through Lilly Support Services ™ for EBGLYSS®, Lilly offers a patient support program including co-pay assistance for eligible, commercially insured patients.

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 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 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 referenced in this press release, they are 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] EBGLYSS. Prescribing Information. Lilly USA, LLC.

[2] Silverberg J, et al. Lebrikizumab every 8 weeks as maintenance dose provides long-lasting response in patients with moderate-to-severe atopic dermatitis. Presented at: Fall Clinical Dermatology Conference; 2025.

[3] Okragly A, et al. Binding, neutralization and internalization of the interleukin-13 antibody, lebrikizumab. Dermatology and Therapy. Published online June 13, 2023. doi:10.1007/s13555-023-00947-7

[4] Ultsch M, et al. Structural basis of signaling blockade by an interleukin-13 antibody lebrikizumab. Journal of Molecular Biology. 2013;425(8):1330-1339. doi:10.1016/j.jmb.2013.01.024

Refer to: Julia Brennan; julia.brennan@lilly.com (Lilly media)
Michael Czapar; czapar_michael_c@lilly.com (Investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/fda-approves-lillys-ebglyss-lebrikizumab-lbkz-for-one-maintenance-dose-every-eight-weeks-in-patients-with-moderate-to-severe-atopic-dermatitis-302795876.html

SOURCE Eli Lilly and Company