Lilly's EBGLYSS® (lebrikizumab-lbkz) single monthly maintenance injection achieved completely clear skin at three years in half of patients with moderate-to-severe atopic dermatitis

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Among EBGLYSS Week 16 responders from the monotherapy trials, 50% achieved highest bar of complete skin clearance (EASI 100 or IGA 0) and 87% achieved almost-clear skin (EASI 90) at three years with single monthly maintenance injection

Additional studies demonstrated EBGLYSS significantly improved itch, skin pain, and sleep loss due to itch for a range of patients with atopic dermatitis

EBGLYSS was approved in the U.S. in September 2024 as a first-line monotherapy biologic treatment option following topical prescription therapies

INDIANAPOLIS, March 7, 2025 /PRNewswire/ -- New results show Eli Lilly and Company's (NYSE: LLY) EBGLYSS achieved deep and sustained response for patients with moderate-to-severe atopic dermatitis (eczema) at three years. These findings from the ADjoin long-term extension study will be presented at the American Academy of Dermatology (AAD) Annual Meeting, taking place March 7-11 in Orlando.[1]

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]

Three-year depth of response data being presented are part of ADjoin, the long-term extension study of the EBGLYSS trials, and include participants who responded to EBGLYSS treatment at Week 16 from ADvocate 1 and ADvocate 2 monotherapy trials. Patients received a maintenance dose of 250 mg EBGLYSS either every two weeks or once monthly (every four weeks) and were assessed for depth of response using IGA 0, EASI 90 and EASI 100.*[1] The approved maintenance dose of EBGLYSS is 250 mg once monthly, after taking EBGLYSS every two weeks for the four-month initial dosing phase (or later once achieving adequate clinical response).[7]

Of the patients who responded to treatment at Week 16 and were receiving once-monthly maintenance dosing, 50% of patients achieved complete skin clearance (EASI 100 or IGA 0) at three years. Additionally, 87% achieved or maintained almost-clear skin (EASI 90) at three years.[1]

Over 83% of Week 16 responders taking EBGLYSS did not require the use of concomitant therapies such as topical corticosteroids (TCS) or topical calcineurin inhibitors (TCI) for the duration of the ADjoin study.[1]

"Healthcare providers are constantly searching for ways to help patients achieve deep, sustainable improvement in the signs and symptoms of their atopic dermatitis," said Raj Chovatiya, M.D., Ph.D., MSCI, Clinical Associate Professor, Rosalind Franklin University Chicago Medical School, Founder and Director of the Center for Medical Dermatology + Immunology Research. "These three-year data show that raising the bar in atopic dermatitis treatment to long-term total skin clearance was an achievable treatment goal for at least half of EBGLYSS Week 16 responders, reinforcing its efficacy as a first-line biologic treatment for people with moderate-to-severe atopic dermatitis uncontrolled by topicals."

Additional study assessments conducted in patients with skin of color (ADmirable) and patients who were previously treated with dupilumab (ADapt) will also be presented at the meeting. Improvements of itch, skin pain (discomfort and soreness) and itch interference on sleep were measured using clinically meaningful thresholds for the validated patient-reported outcomes.[8,9]

In ADmirable, a first-of-its-kind EBGLYSS study specifically designed for people with skin of color and moderate-to-severe atopic dermatitis, nearly 60% of patients achieved significant improvement in itch (Pruritus NRS ≥4-point improvement from baseline) and skin pain (≥4-point improvement from baseline) at Week 16 (58% and 59% respectively). Over 30% of patients saw a reduction in sleep loss due to itch (≥2-point improvement from baseline in Sleep-Loss Scale) at Week 16.[8]

In ADapt, a study of patients taking EBGLYSS who were previously treated with dupilumab, 75% achieved significant improvement in skin pain (≥4-point improvement from baseline) and 62% achieved significant improvement in itch (Pruritus NRS ≥4-point improvement from baseline) at Week 24. Forty-two percent of patients saw a reduction in sleep loss due to itch (≥2-point improvement in Sleep-Loss Scale) at Week 24.[9]

The reported endpoints for all studies were as observed.[1,8,9]

The safety profile in these studies was consistent with previous EBGLYSS Phase 3 studies in patients with moderate-to-severe atopic dermatitis, regardless of dose frequency, and no new safety signals were observed. The majority of adverse events were mild or moderate and did not lead to discontinuation. Reported treatment-related side effects in the studies were conjunctivitis and injection-site reactions.

"We hear from patients with moderate-to-severe atopic dermatitis that they struggle with recurring and unpredictable flares and are looking for treatment options that can provide long-term disease control," said Mark Genovese, M.D., senior vice president of Lilly Immunology development. "EBGLYSS is the only first-line biologic treatment option for patients with disease uncontrolled by topicals to report completely clear skin at three years with a once-monthly maintenance dose. The additional assessments presented at AAD demonstrate significant improvements in disruptive symptoms, such as itch, across a range of patient groups."

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-90=90% reduction in EASI from baseline, EASI-100=100% reduction in EASI from baseline; IGA=Investigator's Global Assessment 0 or 1 ("clear" or "almost clear").

About ADjoin
ADjoin (NCT04392154) evaluated the long-term safety and efficacy of EBGLYSS treatment in patients with moderate-to-severe atopic dermatitis for up to 100 weeks (up to 152 weeks of continuous treatment with the parent studies). Patients taking EBGLYSS who completed any of the parent studies (ADvocate 1 and 2 monotherapy trials, ADhere, ADore, ADopt-VA) were able to enroll in ADjoin. The ADhere parent study included patients taking topical corticosteroids with EBGLYSS as a combination therapy. Patients could also enroll directly into ADjoin without participating in a parent study. Patients in this analysis of the long-term extension trial received a maintenance dose of either EBGLYSS 250 mg every two weeks or once monthly.[1]

About ADmirable
ADmirable (NCT05372419) is a Phase 3b, open-label, 24-week study evaluating the safety and efficacy of EBGLYSS in adults and adolescents (12 to less than 18 years of age and weighing ≥40 kg) with skin of color and moderate-to-severe atopic dermatitis and defining innovative objective measures of pigment, and post-inflammatory hyper and hypopigmentation. Patients enrolled in the ADmirable study received a starting dose of EBGLYSS 500 mg subcutaneously initially and at two weeks followed by 250 mg every two weeks until Week 16. IGA 0,1 or EASI-75 responders at Week 16 received 250 mg once monthly and non-responders continued on 250 mg every two weeks until Week 24. Patients were allowed to stay on low- and mid-potency topical corticosteroids.[8]

About ADapt
ADapt (NCT05369403), is an open-label, Phase 3b, 24-week study that evaluated the efficacy and safety of EBGLYSS in adults and adolescents (12 to less than 18 years of age and weighing ≥40 kg) with moderate-to-severe atopic dermatitis who were previously treated with dupilumab. After discontinuing dupilumab, patients were treated with EBGLYSS and received a starting dose of 500 mg subcutaneously initially and at two weeks followed by 250 mg every two weeks until Week 16. IGA 0,1 or EASI-75 responders at Week 16 received 250 mg once monthly and non-responders continued on 250 mg every two weeks until Week 24. Patients were allowed to stay on low- and mid-potency topical corticosteroids.[9]

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.

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About EBGLYSS
EBGLYSS is a monoclonal antibody that selectively targets and neutralizes IL-13 with high binding affinity and a slow dissociation rate.[5,6,7] 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. Further data results from ADmirable are expected to be shared in 2025.

EBGLYSS was approved in the U.S. by the Food and Drug Administration (FDA) in 2024 as the only 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 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 March 1, Lilly gained coverage with two national pharmacy benefit managers. We are also pursuing similarly broad Medicaid and Medicare coverage as part of Lilly's health equity 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

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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] Simpson E, et al. Raising the Bar of Efficacy in Atopic Dermatitis: Lebrikizumab Maintains Depth of Response Over 3 Years in Week 16 Responders. American Academy of Dermatology Annual Meeting. March 7, 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

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[7] EBGLYSS. Prescribing Information. Lilly USA, LLC.

[8] Alexis A, et al. Lebrikizumab Improves Itch, Skin Pain, and the Interference of Itch on Sleep in Adult and Adolescent Patients with Moderate-to-Severe Atopic Dermatitis and Skin of Color: 16-Week Results from the ADmirable Study. American Academy of Dermatology Annual Meeting. March 7, 2025.

[9] Yosipovitch G, et al. Lebrikizumab Improves Itch, Itch Interference on Sleep and Skin Pain in Patients with Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab. American Academy of Dermatology Annual Meeting. March 7, 2025.

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