Lilly's EBGLYSS (lebrikizumab-lbkz) is the first and only selective IL-13 inhibitor to deliver positive Phase 3 outcomes in patients aged six months to 18 years with moderate-to-severe atopic dermatitis

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In the Phase 3 ADorable-1 study, 63% of patients achieved meaningful skin improvement (EASI-75) and 44% achieved clear or almost clear skin (IGA 0,1) at Week 16

In key secondary endpoints, 39% of patients achieved a high bar of near-complete skin clearance (EASI-90) and 35% achieved significant itch relief (Pruritus NRS ≥4-point improvement)

The safety and tolerability profile of EBGLYSS was consistent with adult and adolescent studies, with no injection site pain reported

INDIANAPOLIS, March 16, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced positive, topline results from the Phase 3 ADorable-1 trial evaluating the safety and efficacy of EBGLYSS (lebrikizumab-lbkz) in pediatric patients with moderate-to-severe atopic dermatitis. EBGLYSS met the primary and key secondary endpoints at Week 16, improving disease severity while delivering skin clearance and relief from persistent itch. Atopic dermatitis is more common in children than adults, affecting 9.6 million children in the U.S., one-third of whom have moderate-to-severe disease.[1] Lilly plans to submit these data to U.S. and global regulators for a potential label update.

EBGLYSS is an interleukin-13 (IL-13) inhibitor that selectively blocks IL-13 signaling with high binding affinity and slow dissociation rate.[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 ADorable-1, participants were randomized to receive placebo or a weight-based dose of EBGLYSS. Topical corticosteroids were required beginning two weeks before randomization and throughout the 16-week study but could be decreased or stopped once patients achieved IGA 2 or less. The co-primary endpoints in ADorable-1 were EASI-75 and IGA 0,1 at Week 16. Key secondary endpoints included an even greater clinical improvement in disease severity (EASI-90) and itch relief (Pruritus NRS ≥4-point improvement).

Key efficacy results in ADorable-1 at Week 16		
	EBGLYSS*	**Placebo**
EASI-75**	63 %	22 %
IGA 0,1 and a reduction ≥2 points from baseline†	44 %	15 %
EASI-90‡	39 %	11 %
Pruritus NRS ≥4-point improvement§ in patients 6 years and older with score ≥4 at baseline	35 %	6 %

* Includes all EBGLYSS dosing regimens

** EASI=Eczema Area and Severity Index; EASI-75=75% reduction in EASI from baseline

† IGA 0,1=Investigator's Global Assessment 0 or 1 ("clear" or "almost clear")

‡ EASI-90=90% reduction in EASI from baseline

§ Pruritus NRS=Numeric Rating Scale rating itch from 0-10 with 10 being worst imaginable itch within the past 24 hours

"Children with moderate-to-severe atopic dermatitis often endure relentless skin flares, itch and discomfort that can disrupt play, school and daily life for patients and caregivers," said Adrienne Brown, executive vice president and president, Lilly Immunology. "EBGLYSS has already changed what's possible for adults and adolescents, delivering durable results that help patients flare less with the option of monthly maintenance dosing. Now, these data show EBGLYSS also provided disease control in pediatric patients, a critical milestone that, if approved, could bring profound relief to these patients and their families."

The safety of EBGLYSS was consistent with the known profile in adult and adolescent patients, with no new safety signals observed. The most common adverse events occurring in ≥5% of participants were upper respiratory tract infections and nasopharyngitis, with no numerical imbalance between treatment groups. Injection site reactions were reported similarly in the EBGLYSS and placebo arms, with no injection site pain reported.

"Despite the high prevalence of moderate-to-severe atopic dermatitis in infants and young children, they have fewer approved treatment options than adults and adolescents," said Amy Paller, M.D., chair, department of dermatology at Northwestern University and ADorable study investigator. "The topline results from ADorable-1 offer hope for these young patients, delivering near-complete skin clearance and significant itch relief with a highly selective medicine that targets the underlying inflammation that drives this chronic disease."

The ADorable clinical program is ongoing. Additional results from ADorable-1 and ADorable-2, a 52-week extension study of patients enrolled in ADorable-1, will be disclosed later this year.

Lilly continues to raise the standard of care in dermatology and boldly invest in the next wave of immunology innovation, which includes big bets on next-generation modalities, the targeted expansion of small molecules and advancing novel science that uncovers the potential of incretins. Lilly

recently shared topline findings from the TOGETHER-PsO and TOGETHER-PsA trials investigating the efficacy and safety of treating adults with psoriatic disease and obesity with both ixekizumab and an incretin-based therapy. Lilly's investigational therapies include DC-853, a novel oral IL-17 inhibitor being studied for psoriasis, and eltrekibart, a novel monoclonal antibody that targets neutrophil-driven inflammation and is being assessed in hidradenitis suppurativa.

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.

About ADorable-1
ADorable-1 (NCT05559359) is a randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy and safety of EBGLYSS in pediatric patients with moderate-to-severe atopic dermatitis, including infants and children as young as six months. Participants (N=363) were randomized to receive placebo or a weight-based dose of EBGLYSS. Topical corticosteroids were required beginning two weeks before randomization and throughout the 16-week study, but could be decreased or stopped once patients achieved IGA 2 or less. Data from ADorable-1 are intended to support a potential label expansion of EBGLYSS in younger pediatric populations.

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 in atopic dermatitis consists of seven key global studies evaluating over 1,600 patients, including two monotherapy studies (ADvocate 1 and 2), a combination study with topical corticosteroids (ADhere), long-term extension (ADjoin), adolescent open-label (ADore) and pediatric (ADorable 1 and 2) studies. Further data results from ADorable are expected later this year. EBGLYSS is also being studied in allergic rhinitis and chronic rhinosinusitis with nasal polyps.

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 with the option of monotherapy that offers 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) which can be used with or without topical corticosteroids.[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 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, 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.

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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

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.

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Refer to: Kelly Hoffman; kelly.hoffman@lilly.com; 765-736-2555 (Lilly media)
Michael Czapar; czapar_michael_c@lilly.com; 317-617-0983 (Investors)

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