Ebglyss™ (lebrikizumab-lbkz) – New drug approval

- On September 13, 2024, Eli Lilly announced the FDA approval of Ebglyss (lebrikizumab-lbkz), for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
    - Ebglyss can be used with or without topical corticosteroids.
- Ebglyss is the second interleukin-13 (IL-13) antagonist approved for atopic dermatitis. LEO Pharma's Adbry® (tralokinumab-ldrm) was approved in December 2021.
- The efficacy of Ebglyss was established in a three randomized, double-blind, placebo-controlled studies (ADvocate 1, ADvocate 2, and ADhere) in a total of 1,062 patients 12 years of age and older with moderate-to-severe atopic dermatitis not adequately controlled by topical medication(s) and who were candidates for systemic therapy. ADvocate 1 and ADvocate 2 were monotherapy studies and ADhere was a concomitant therapy study (all patients received background therapy with topical corticosteroids). The primary endpoint in the studies was the proportion of patients who achieved an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and at least a 2-point improvement from baseline at week 16.
    - In ADvocate 1, 43% and 13% of patients met the primary endpoint in the Ebglyss and placebo arms, respectively (treatment difference 30, 95% CI: 22, 38).
    - In ADvocate 2, 33% and 11% of patients met the primary endpoint in the Ebglyss and placebo arms, respectively (treatment difference 22, 95% CI: 14, 30).
    - In ADhere (the concomitant therapy study), the results at week 16 were consistent with the results in the monotherapy trials.
- To evaluate the maintenance and durability of response in the monotherapy studies, patients originally randomized to Ebglyss who achieved an IGA score of 0 or 1, or at least a 75% reduction in Eczema Area and Severity Index from baseline (EASI-75) at week 16 and did not require rescue therapy were re-randomized to an additional 36 weeks of either a maintenance dose of Ebglyss every 2 weeks, Ebglyss every 4 weeks, or placebo.
    - For ADvocate 1 and at week 52, an IGA of 0 or 1 was achieved in 76%, 74%, and 47% of patients in the Ebglyss every 2 weeks, Ebglyss every 4 weeks, and placebo arms.
    - For ADvocate 2 and at week 52, an IGA of 0 or 1 was achieved in 65%, 81%, and 50% of patients in the Ebglyss every 2 weeks, Ebglyss every 4 weeks, and placebo arms.
- Warnings and precautions for Ebglyss include hypersensitivity, conjunctivitis and keratitis, parasitic (helminth) infections, and vaccinations (Ebglyss may alter a patient's immunity and increase the risk of infection following administration of live vaccines).
- The most common adverse reactions (≥ 1%) with Ebglyss use were conjunctivitis, injection site reactions, and herpes zoster.
- The recommended dosage of Ebglyss is an initial subcutaneous (SC) dose of 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. The maintenance dosage is 250 mg SC every four weeks.

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- Eli Lilly plans to launch Ebglyss in the coming weeks. Ebglyss will be available as a 250 mg/2 mL single-dose prefilled pen and single-dose prefilled syringe.