Adbry® (tralokinumab-ldrm) – Expanded indication

- On December 14, 2023, the FDA approved Leo Pharma's Adbry (tralokinumab-ldrm), for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.
    - Adbry was previously approved for this indication in adults only.
- The approval of Adbry for the expanded indication was based on ECZTRA 6, a randomized, double-blind, placebo-controlled study in 289 pediatric patients 12 to 17 years of age with moderate-to-severe atopic dermatitis. The primary endpoints were the proportion of patients with Investigator's Global Assessment (IGA) 0 or 1 at week 16 ("clear" or "almost clear") and the proportion of patients with Eczema Area and Severity Index (EASI)-75 (improvement of at least 75% in EASI from baseline) at week 16.
    - IGA response was achieved in 21% and 4% of patients with Adbry and placebo, respectively (difference 18, 95% CI: 8, 27).
    - EASI-75 was achieved in 29% and 6% of patients with Adbry and placebo, respectively (difference 23, 95% CI: 12, 33).
- In pediatric patients 12 to 17 years old, the recommended initial subcutaneous (SC) dose of Adbry is 300 mg (two 150 mg injections). The subsequent dose is 150 mg (one 150 mg injection) every other week.
    - Adbry is intended for use under the guidance of a healthcare provider. A patient may self-inject after training in SC injection technique. In pediatric patients 12 years of age and older, it is recommended that Adbry be given by or under supervision of an adult.
    - Refer to the Adbry drug label for adult dosing.