Adbry™ (tralokinumab-ldrm) – New drug approval

- On December 28, 2021, Leo Pharma announced the FDA approval of Adbry (tralokinumab-ldrm), for the treatment of moderate-to-severe atopic dermatitis in adult patients 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.
- Atopic dermatitis is a chronic, inflammatory, skin disease characterized by intense itch and eczematous lesions. Type 2 cytokines, including interleukin (IL)-13 are believed to play a central role in the key aspects of atopic dermatitis pathophysiology.
- Adbry is a novel human monoclonal antibody that binds to the IL-13 cytokine.
- The efficacy of Adbry was established in three randomized, double-blind, placebo-controlled studies in 1,934 adult patients with moderate-to-severe atopic dermatitis not adequately controlled by topical medication(s). In all three studies, patients received subcutaneous (SC) injections of Adbry 600 mg or placebo on day 0, followed by 300 mg every other week or placebo for 16 weeks. ECZTRA 1 and ECZTRA 2 evaluated Adbry as monotherapy and ECZTRA 3 evaluated Adbry in combination with topical corticosteroids. The primary endpoints were the proportion of patients achieving an Investigator's Global Assessment (IGA) 0 or 1 ("clear" or "almost clear") and the proportion of patients with Eczema Area and Severity Index (EASI)-75 (improvement of at least 75% in EASI score from baseline) at week 16.

	ECZTRA 1		ECZTRA 2		ECZTRA 3	
	Adbry	Placebo	Adbry	Placebo	Adbry	Placebo
IGA 0 or 1	16%	7%	21%	9%	38%	27%
Difference from placebo (95% CI)	9 (4, 13)		12 (7, 17)		11 (1, 21)	
EASI-75	25%	13%	33%	10%	56%	37%
Difference from placebo (95% CI)	12 (6, 18)		22 (17, 28)		20 (9, 30)	

- Warnings and precautions for Adbry include hypersensitivity, conjunctivitis and keratitis, parasitic (helminth) infections, and risk of infection with live vaccines.
- The most common adverse reactions (≥ 1%) with Adbry use were upper respiratory tract infections, conjunctivitis, injection site reactions, and eosinophilia.
- The recommended SC dose of Adbry is:
    - An initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week.
    - After 16 weeks of treatment, for patients with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered.

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- Adbry is intended for use under the guidance of a healthcare provider. A patient may self-inject Adbry after training in SC injection technique.

- All age-appropriate vaccinations should be completed as recommended by current immunization guidelines prior to initiating treatment with Adbry.

- Leo Pharma plans to launch Adbry by February 2022. Adbry will be available as a 150 mg/mL solution in a single-dose prefilled syringe.