Cosentyx® (secukinumab) – Expanded indication

- On May 28, 2021, the FDA approved Novartis' Cosentyx (secukinumab), for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.
    - Cosentyx was previously approved for this indication in adults only.
- Cosentyx is also approved in adults for psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.
- The approval of Cosentyx for the expanded indication was based on a 52-week, randomized, double-blind, placebo and active-controlled study in 162 pediatric patients 6 years of age and older, with severe plaque psoriasis. Patients were randomized to receive placebo, Cosentyx, or a biologic active control. The co-primary endpoints were the proportion of patients who achieved a reduction in Psoriasis Area Severity Index (PASI) score of at least 75% (PASI 75) from baseline to week 12 and the proportion of patients who achieved an Investigator's Global Assessment (IGA) modified 2011 score of 'clear' or 'almost clear' (0 or 1) with at least a 2 point improvement from baseline to week 12.
    - PASI 75 response was achieved in 70% of patients receiving Cosentyx vs. 15% of patients receiving placebo.
    - IGA response was achieved in 56% of patients receiving Cosentyx vs. 5% of patients receiving placebo.
- The recommended dose of Cosentyx for the treatment of plaque psoriasis in pediatric patients is based on body weight and administered by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks. In patients less than 50 kg, the recommended dose is 75 mg. In patients greater than or equal to 50 kg, the recommended dose is 150 mg.
    - Refer to the Cosentyx drug label for dosing for all its other indications.