Cosentyx® (secukinumab) – New indication, expanded indication

- On December 23, 2021, Novartis announced the FDA approval of Cosentyx (secukinumab), for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

- In addition, the FDA approved Cosentyx for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.

    — Cosentyx was previously approved for this indication in adults only.

- Cosentyx is also approved for the treatment of:

    — Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy
    — Adult patients with active ankylosing spondylitis
    — Adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

- The approval of Cosentyx for the new and expanded indications was based on a 3-part, randomized, double-blind, placebo-controlled, event-driven study in patients 2 to < 18 years of age with active ERA or juvenile psoriatic arthritis (JPsA). The study consisted of an open-label portion (Part 1) followed by randomized withdrawal (Part 2) followed by open-label treatment (Part 3). The primary endpoint was time to flare in Part 2. Disease flare was defined as a ≥ 30% worsening in at least three of the six JIA ACR response criteria and ≥ 30% improvement in not more than one of the six JIA ACR response criteria and a minimum of two active joints.

    — During Part 2, a total of 11 JPsA patients in the placebo group experienced a flare event compared with 4 JPsA patients in the Cosentyx group. The risk of flare was reduced by 85% for patients on Cosentyx vs. placebo (hazard ratio [HR] 0.15, 95% CI: 0.04 to 0.56).
    — During Part 2, a total of 10 ERA patients in the placebo group experienced a flare event compared with 6 ERA patients in the Cosentyx group. The risk of flare was reduced by 53% for patients on Cosentyx vs. placebo (HR 0.47, 95% CI: 0.17 to 1.32).

- For pediatric patients with PsA and ERA, the recommended dose of Cosentyx is based on body weight and administered by subcutaneous (SC) injection at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

    — For patients weighing ≥ 15 kg and < 50 kg the recommended dose is 75 mg
    — For patients weighing ≥ 50 kg the recommended dose is 150 mg.

- Refer to the Cosentyx drug label for dosing for all its other indications and uses.