Cosentyx® (secukinumab) – New indication

- On June 17, 2020, Novartis announced the FDA approval of Cosentyx (secukinumab), for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

- Cosentyx is also approved for the treatment of adult patients with moderate to severe plaque psoriasis, active psoriatic arthritis, and active ankylosing spondylitis.

- The efficacy of Cosentyx was evaluated in a randomized, double-blind study of 555 adult patients with nr-axSpA. Patients received Cosentyx with a loading dose, Cosentyx without a loading dose or placebo. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS40) at week 52.

    — A total of 70% of patients receiving Cosentyx without a loading dose, 62% of patients receiving Cosentyx with a loading dose vs. 36% of placebo patients met the primary endpoint (treatment difference vs. placebo: Cosentyx without a load: 19% [95% CI: 10, 28] and Cosentyx with a load: 14% [95% CI: 5, 23]).

- The dose of Cosentyx for nr-axSpA is administered with or without a loading dose as a subcutaneous (SC) injection as follows:

    — With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
    — Without a loading dosage: 150 mg every 4 weeks.
    — Cosentyx is intended for use under the guidance and supervision of a physician. Patients may self-inject after proper training in SC injection technique using the Sensoready pen or prefilled syringe and when deemed appropriate.
    — The lyophilized powder for reconstitution is for healthcare provider use only.
    — Refer to the Cosentyx drug label for dosing recommendations for its other indications.