Taltz® (ixekizumab) – New indication

- On June 1, 2020, Eli Lilly announced the FDA approval of Taltz (ixekizumab), for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

- Taltz is also approved for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis, adult patients with active psoriatic arthritis, and adult patients with active ankylosing spondylitis (AS).

- Axial spondyloarthritis (axSpA) includes both AS and nr-axSpA. For patients with AS, the disease is characterized by the presence of structural damage of the sacroiliac joints that appears on an X-ray, while patients with nr-axSpA do not have clearly detectable structural damage radiographically.

    — It is estimated that 2.3 million people in the U.S. have axSpA, and approximately half of those individuals live with nr-axSpA.

- The efficacy of Taltz for nr-axSpA was demonstrated in a double-blind, 52-week placebo-controlled study in 201 patients ≥ 18 years of age with active axSpA. Patients received Taltz or placebo. The primary endpoint was the percentage of patients achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at week 52.

    — The primary endpoint was met in 30.2% of patients treated with Taltz vs. 13.3% of patients treated with placebo (Difference from placebo: 16.9%; 95% CI: 5.6, 28.1).

- The recommended dose of Taltz for nr-axSpA is 80 mg by subcutaneous (SC) injection every 4 weeks.

    — Taltz is intended for use under the guidance and supervision of a physician. Adult patients may self-inject or caregivers may give injections of Taltz 80 mg after training in SC injection technique using the autoinjector or prefilled syringe.
    — Refer to the Taltz drug label for dosing for all its other indications.