Taltz® (ixekizumab) – Expanded indication

- On March 30, 2020, Eli Lilly announced the FDA approval of Taltz (ixekizumab), for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
    - Taltz was previously approved for this indication in adult patients only.
- Taltz is also approved for the treatment of adult patients with active psoriatic arthritis and adult patients with active ankylosing spondylitis.
- The approval of Taltz for the expanded indication was based on a randomized, double-blind, placebo-controlled trial in 171 pediatric patients 6 to less than 18 years of age, with moderate-to-severe plaque psoriasis. Response to treatment was assessed at 12 weeks of therapy and was defined by the proportion of patients who achieved a static Physician Global Assessment (sPGA) score of "0" (clear) or "1" (almost clear) with at least a 2 point improvement from baseline and the proportion of patients that achieved a reduction in Psoriasis Area and Severity Index (PASI) score of at least 75% (PASI 75) from baseline.
    - The sPGA endpoint was achieved in 81% of patients receiving Taltz vs. 11% receiving placebo.
    - The PASI 75 endpoint was achieved in 89% of patients receiving Taltz vs. 25% receiving placebo.
- The recommended dose of Taltz for the treatment of pediatric plaque psoriasis is based on the weight. Taltz is administered by subcutaneous injection every 4 weeks.

Pediatric patient's weight	Starting dose (week 0)	Dose every 4 weeks thereafter
Greater than 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
Less than 25 kg	40 mg	20 mg

- Refer to the Taltz drug label for dosing for all its other indications.