Taltz® (ixekizumab) – New indication

- On August 26, 2019, Eli Lilly announced the FDA approval of Taltz (ixekizumab), for the treatment of adult patients with active ankylosing spondylitis (AS).

- Taltz is also approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and adult patients with active psoriatic arthritis.

- AS is a type of spondyloarthritis that affects the pelvic joints and spine, and can be characterized by chronic inflammatory back pain, stiffness and impaired function and mobility.

    — AS is estimated to impact approximately 1.6 million people in the U.S.

- The approval of Taltz for the new indication was based on two randomized, double-blind studies in adult patients with AS. Study 1 evaluated 341 biologic-naive patients, who were treated with either Taltz 80 mg or 160 mg at week 0 followed by 80 mg every 2 weeks (Q2W) or 4 weeks (Q4W), adalimumab 40 mg every 2 weeks, or with placebo. Study 2 evaluated 316 TNF-inhibitor experienced patients. Patients in study 2 were treated with Taltz 80 mg or 160 mg at week 0 followed by 80 mg Q2W or Q4W, or with placebo. The primary endpoint in both studies was the percentage of patients achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at week 16.

    — In both studies, patients treated with Taltz 80 mg Q4W demonstrated greater improvements in ASAS40 and ASAS20 responses vs. placebo at week 16.

	Study 1 (biologic-naïve)			Study 2 (TNF-inhibitor experienced)		
	Taltz 80 mg Q4W (n = 81)	Placebo (n = 87)	Difference (95% CI)	Taltz 80 mg Q4W (n = 114)	Placebo (n = 104)	Difference (95% CI)
ASAS20*, %	64	40	24 (9, 39)	48	30	18 (6, 31)
ASAS40*, %	48	18	30 (16, 43)	25	13	13 (3, 23)

*ASAS20 response is defined as a ≥ 20% improvement and an absolute improvement from baseline of ≥ 1 units (range 0 to 10) in ≥ 3 of 4 domains (patient global, spinal pain, function, and inflammation), and no worsening of ≥ 20% and ≥ 1 unit (range 0 to 10) in the remaining domain. An ASAS40 response is defined as a ≥ 40% improvement and an absolute improvement from baseline of ≥ 2 units in ≥ 3 of 4 domains without any worsening in the remaining domain.

- The recommended dose of Taltz for the treatment of AS is 160 mg by subcutaneous (SC) injection (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.

    — Conventional disease-modifying antirheumatic drug (eg, sulfasalazine), corticosteroids, non-steroidal anti-inflammatory drugs, and/or analgesics may be used during treatment with Taltz.
    — Taltz is intended for use under the guidance and supervision of a physician. Patients may self-inject 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.