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Taltz (ixekizumab) Injection
Clinical Update

Clinical Update: Lilly's Taltz (ixekizumab) Receives U.S. FDA Approval for the Treatment of Pediatric Patients with Moderate to Severe Plaque Psoriasis.

FDA approval date: March 26, 2020

Taltz® (ixekizumab) is a monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Taltz inhibits the release of pro-inflammatory cytokines and chemokines.

The U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for Taltz (ixekizumab) injection, 80 mg/mL for the treatment of pediatric patients (ages 6 to under 18) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Psoriasis affects nearly 8 million people in the U.S. Many people living with psoriasis develop symptoms during childhood. Overall, the safety profile observed in pediatric patients with plaque psoriasis treated with Taltz every four weeks is consistent with the safety profile in adult patients with plaque psoriasis, with the exception of the frequencies of conjunctivitis (3%), influenza (2%) and urticaria (2%).

The FDA approval of Taltz in pediatric patients with moderate to severe plaque psoriasis was based on a Phase 3, multicenter, randomized, double-blind, placebo-controlled study to evaluate safety, tolerability and efficacy of Taltz in patients from 6 to under 18 years of age. The co-primary endpoints of the study were the proportion of patients achieving a 75 percent improvement from baseline on their Psoriasis Area and Severity Index score (PASI 75) and a static Physician's Global Assessment of clear or almost clear skin (sPGA 0,1) at Week 12. Key secondary endpoints included the proportion of patients achieving PASI 90, sPGA 0 and PASI 100 at Week 12, and at least a four-point improvement in Itch numeric rating scale (Itch NRS ≥ 4) among patients with baseline Itch NRS ≥ 4 at Week 12, as well as PASI 75 and sPGA 0,1 at Week 4.