Ilumya™ (tildrakizumab-asmn) – New drug approval

- On March 21, 2018, Sun Pharma announced the FDA approval of Ilumya (tildrakizumab-asmn) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

- Psoriasis is a chronic immune disease that appears on the skin. It is a non-contagious disorder that speeds the growth cycle of skin cells and results in thick scaly areas of skin. The most common form, affecting about 80% to 90% of people living with psoriasis, is called plaque psoriasis.

- Ilumya selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor leading to inhibition of the release of pro-inflammatory cytokines and chemokines.

- The efficacy and safety of Ilumya were demonstrated in two placebo-controlled studies of 926 patients with plaque psoriasis. The co-primary endpoints were the proportion of patients who achieved at least a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) composite score and the proportion of patients with a Physician Global Assessment (PGA) of 0 or 1 and at least a 2-point improvement at week 12.

    — Both clinical studies demonstrated improvements with Ilumya in the primary endpoints vs. placebo (PASI 75: 64% and 61% vs. 6% in both studies; PGA of 0 or 1: 58% and 55% vs. 7% and 4%, respectively).

- Warnings and precautions of Ilumya include hypersensitivity, infections, pretreatment evaluation for tuberculosis, and immunizations.

- The most common adverse reactions (≥ 1%) with Ilumya use were upper respiratory infections, injection site reactions, and diarrhea.

- The recommended dose of Ilumya is 100 mg administered by a healthcare provider as a subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter.

- Sun Pharma's launch plans for Ilumya are pending. Ilumya will be available as a 100 mg/mL solution in a single-dose prefilled syringe.