Bimzelx® (bimekizumab-bkzx) – New drug approval

- On October 18, 2023, UCB announced the FDA approval of Bimzelx (bimekizumab-bkzx), for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

- Bimzelx is an interleukin (IL)-17 A and F antagonist. IL-17A and IL-17F are naturally occurring cytokines that are involved in normal inflammatory and immune responses.

- The efficacy of Bimzelx was established in three randomized, double-blind studies (Trial-Ps-1, Trial-Ps-2, and Trial-Ps-3) in a total of 1,480 patients with moderate to severe plaque psoriasis.

- In Trial-Ps-1, 567 patients were randomized to Bimzelx, Stelara® (ustekinumab), or placebo. In Trial-Ps-2, 435 patients were randomized to Bimzelx or placebo. In these two studies, the two primary endpoints were the (1) the proportion of patients who achieved an Investigator's Global Assessment (IGA) score of 0 ("clear") or 1 ("almost clear") with at least a 2-grade improvement from baseline, and (2) the proportion of patients who achieved at least a 90% reduction from baseline Psoriasis Area and Severity Index (PASI90). Both primary endpoints were measured at week 16.

    - In Trial-Ps-1, IGA response was achieved in 84% and 5% of patients with Bimzelx and placebo, respectively (treatment difference 79, 95% CI: 73, 85). In Trial-Ps-2, IGA response was achieved in 93% and 1% of patients, respectively (treatment difference 91, 95% CI: 88, 95).
    - In Trial-Ps-1, PASI90 was achieved in 85% and 5% of patients with Bimzelx and placebo, respectively (treatment difference 80, 95% CI: 74, 86). In Trial-Ps-2, PASI90 was achieved in 91% and 1% of patients, respectively (treatment difference 90, 95% CI: 86, 93).

- Warnings and precautions for Bimzelx include suicidal ideation and behavior; infections; tuberculosis; liver biochemical abnormalities; inflammatory bowel disease; and immunizations.

- The most common adverse reactions (≥ 1%) with Bimzelx use were upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

- The recommended dose of Bimzelx is 320 mg (given as 2 subcutaneous injections of 160 mg each) at weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter.

    - For patients weighing ≥ 120 kg, a dosage of 320 mg every 4 weeks after week 16 can be considered.
    - Bimzelx may be administered by a healthcare professional, or a patient may self-inject after proper training.

- UCB plans to launch Bimzelx in approximately one month. Bimzelx will be available as a 160 mg/mL single-dose prefilled syringe or single-dose prefilled autoinjector.