Bimzelx® (bimekizumab-bkzx) – New indication

- On November 20, 2024, UCB announced the FDA approval of Bimzelx (bimekizumab-bkzx), for the treatment of adults with moderate to severe hidradenitis suppurativa.

- Bimzelx is also approved for the treatment of plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis.

- The approval of Bimzelx for the new indication was based on two randomized, double-blind, placebo-controlled studies (Trial HS-1 and Trial HS-2) in 1,014 adult patients with moderate to severe hidradenitis suppurativa. Patients received Bimzelx 320 mg every 2 weeks (Q2W) for 48 weeks, or Bimzelx 320 mg every 4 weeks (Q4W) up to week 48, or Bimzelx 320 mg Q2W to week 16, followed by 320 mg Q4W up to week 48, or placebo. The primary endpoint in both trials was the Hidradenitis Suppurativa Clinical Response 50 (HiSCR50) at week 16, defined by at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess or draining tunnel count relative to baseline.

    - In patients receiving Bimzelx 320 mg Q2W in Trial HS-1, the HiSCR50 was 48% with Bimzelx vs. 29% with placebo (difference 18, 95% CI: 6, 30).
    - In patients receiving Bimzelx 320 mg Q2W in Trial HS-2, the HiSCR50 was 52% with Bimzelx vs. 32% with placebo (difference 20, 95% CI: 8, 32).

- The most common adverse reactions (≥ 1%) with Bimzelx use for hidradenitis suppurativa were upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

- The recommended dosage of Bimzelx for hidradenitis suppurativa is 320 mg by subcutaneous injection at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter.

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