Bimzelx® (bimekizumab) – New indications

- On September 23, 2024, UCB announced the FDA approval of Bimzelx (bimekizumab), for three new indications – treatment of adult patients with:
    - Active psoriatic arthritis (PsA)
    - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
    - Active ankylosing spondylitis (AS).
- Bimzelx is also approved for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- The approval of Bimzelx for PsA was based on two randomized, double-blind, placebo-controlled studies (PsA-1 and PsA-2) in 1,112 patients 18 years and older with active PsA. For both studies, the primary endpoint was the proportion of patients who achieved an America College of Rheumatology (ACR) 50 response at week 16.
    - In PsA-1, ACR 50 response was achieved in 43.9% and 10.0% of patients in the Bimzelx and placebo arms, respectively (treatment difference 33.9, 95% CI: 28.0, 39.7; $p < 0.001$).
    - In PsA-2, ACR 50 response was achieved in 43.4% and 6.8% of patients in the Bimzelx and placebo arms, respectively (treatment difference 36.7, 95% CI: 29.4, 44.0; $p < 0.001$).
- The approval of Bimzelx for nr-axSpA was based on a randomized, double-blind, placebo-controlled study in 254 adult patients 18 years of age and older with active nr-axSpA. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS 40) at week 16.
    - ASAS 40 response was achieved in 47.7% and 21.4% of patients in the Bimzelx and placebo arms, respectively (treatment difference 26.2, 95% CI: 15.0, 37.5; $p < 0.001$).
- The approval of Bimzelx for AS was based on a randomized, double-blind, placebo-controlled study in 332 adult patients 18 years of age and older with active AS. The primary endpoint was ASAS 40 at week 16.
    - ASAS 40 response was achieved in 44.8% and 22.5% of patients in the Bimzelx and placebo arms, respectively (treatment difference 22.3, 95% CI: 12.1, 32.4; $p < 0.001$).
- The most common adverse reactions (≥ 2%) with Bimzelx use were:
    - PsA: upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infection
    - nr-axSpA: upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsilitis, increase transaminase, and urinary tract infection
    - AS: upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash and vulvovaginal mycotic infection.
- The recommended dose of Bimzelx for the treatment of its new indications is 160 mg by subcutaneous injection every 4 weeks.

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— For PsA patients with coexistent moderate to severe plaque psoriasis, the dosing regimen for adult patients with plaque psoriasis should be used. Refer to the drug label for complete dosing recommendations for plaque psoriasis.