Bimzelx® (bimekizumab-bkzx) – New device approvals

- On October 14, 2024, UCB announced the FDA approval of a 2 mL pre-filled syringe and pre-filled autoinjector, each containing 320 mg of Bimzelx® (bimekizumab-bkzx).
    - These new device presentations add to the currently available 1 mL administration options, each containing 160 mg of Bimzelx.
- The new 320 mg devices mean that patients requiring a 320 mg dose of Bimzelx will have options for single-injection administration.
- Bimzelx is approved for the treatment of plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis.
- For plaque psoriasis, the recommended dosage of Bimzelx is 320 mg by subcutaneous (SC) injection at weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing 120 kg or more, a dosage of 320 mg every 4 weeks after week 16 can be considered.
- For psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis, the recommended dosage of Bimzelx is 160 mg by SC injection every 4 weeks.
- UCB plans to launch the 320 mg device presentations in the first quarter of 2025.