Stoboclo® (denosumab-bmwo) – New biosimilar approval

- On March 3, 2025, Celltrion announced the FDA approval of Stoboclo (denosumab-bmwo), biosimilar to Amgen's Prolia® (denosumab).
    - Stoboclo is the third FDA-approved biosimilar to Prolia.
    - Sandoz's Jubbonti® (denosumab-bbdz) and Samsung Bioepis' Ospomyv™ (denosumab-dssb) were previously approved as biosimilars to Prolia.
- Stoboclo, Ospomyv, Jubbonti and Prolia share the following indications:
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture
    - Treatment to increase bone mass in men with osteoporosis at high risk for fracture
    - Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
    - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
    - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
- The approval of Stoboclo is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Prolia.
- Like Prolia, Stoboclo carries a boxed warning for severe hypocalcemia in patients with advanced kidney disease.
- Stoboclo is contraindicated in patients with:
    - Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with Stoboclo.
    - Pregnancy: Denosumab products may cause fetal harm when administered to a pregnant woman.
    - Hypersensitivity: Reactions have included anaphylaxis, facial swelling, and urticaria.
- Warnings and precautions for Stoboclo include severe hypocalcemia and mineral metabolism changes; drug products with same active ingredient; hypersensitivity; osteonecrosis of the jaw; atypical subtrochanteric and diaphyseal femoral fractures; multiple vertebral fractures following discontinuation of treatment; serious infections; dermatologic adverse reactions; musculoskeletal pain; suppression of bone turnover; and hypercalcemia in pediatric patients with osteogenesis imperfecta.
- The most common adverse reactions (> 5% and more common than placebo) with Stoboclo use in postmenopausal osteoporosis were back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis.
- The most common adverse reactions (> 5% and more common than placebo) with Stoboclo use in male osteoporosis were back pain, arthralgia, and nasopharyngitis.
- The most common adverse reactions (> 3% and more common than active-control group) with Stoboclo use in glucocorticoid-induced osteoporosis were back pain, hypertension, bronchitis, and headache.

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- The most common adverse reactions (> 5% and more common than placebo) with Stoboclo use in male osteoporosis were back pain, arthralgia, and nasopharyngitis.
- The most common adverse reactions (≥ 10% and more common than placebo) with Stoboclo use in patients with bone loss due to hormone ablation for cancer were arthralgia and back pain.
- The recommended dosage of Stoboclo is 60 mg administered as a single subcutaneous injection once every 6 months.
    - Stoboclo should be administered by a healthcare professional.
    - All patients should receive calcium 1,000 mg daily and at least 400 IU vitamin D daily.
- Celltrion's launch plans for Stoboclo are pending. Stoboclo will be available as a 60 mg/mL solution in a single-dose prefilled syringe.
    - A confidential settlement agreement signed between Amgen and Celltrion allows for launch of Stoboclo as early as June 1, 2025.

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