Osenvelt® (denosumab-bmwo) – New biosimilar approval

- On March 3, 2025, Celltrion announced the FDA approval of Osenvelt (denosumab-bmwo), biosimilar to Amgen's Xgeva® (denosumab).
    - Osenvelt is the third FDA-approved biosimilar to Xgeva.
    - Sandoz's Wyost® (denosumab-bbdz) and Samsung Bioepis' Xbryk™ (denosumab-dssb) were previously approved as biosimilars to Xgeva.
- Osenvelt, Xbryk, Wyost and Xgeva share the following indications:
    - Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
    - Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
    - Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
- The approval of Osenvelt is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Xgeva.
- Osenvelt is contraindicated in patients with:
    - Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with Osenvelt.
    - Hypersensitivity.
- Warnings and precautions for Osenvelt include drug products with same active ingredient; osteonecrosis of the jaw; atypical subtrochanteric and diaphyseal femoral fractures; hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons; multiple vertebral fractures following discontinuation of treatment; and embryo-fetal toxicity.
- The most common adverse reactions (≥ 25%) with Osenvelt use in bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea.
- The most common adverse reactions (≥ 10%) with Osenvelt use in multiple myeloma were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- The most common adverse reactions (≥ 10%) with Osenvelt use in giant cell tumor of the bone were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- The most common adverse reactions (≥ 20%) with Osenvelt use in hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.
- The recommended dosage of Osenvelt in multiple myeloma and bone metastasis from solid tumors is 120 mg administered as a subcutaneous (SC) injection every 4 weeks in the upper arm, upper thigh, or abdomen.

Continued . . .

- The recommended dosage of Osenvelt in giant cell tumor of the bone and hypercalcemia of malignancy is 120 mg administered SC every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy.
- Celltrion's launch plans for Osenvelt are pending. Osenvelt will be available as a 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial.
- A confidential settlement agreement signed between Amgen and Celltrion allows for launch of Osenvelt as early as June 1, 2025.

Optum