FDA Grants Interchangeability Designation to Denosumab Biosimilars Stoboclo and Osenvelt

Key Takeaways

- The FDA designated Stoboclo and Osenvelt as interchangeable biosimilars to Prolia and Xgeva, effective October 29, 2025.
- Stoboclo and Osenvelt are indicated for osteoporosis, cancer-related skeletal events, and other conditions, mirroring their reference products.
- Clinical trials confirmed the equivalence of CT-P41 to denosumab in efficacy, pharmacodynamics, and safety for postmenopausal osteoporosis.
- Interchangeability allows substitution at pharmacies without prescriber consultation, subject to state laws, enhancing treatment affordability and accessibility.

The FDA designates Stoboclo and Osenvelt as interchangeable biosimilars for denosumab, enhancing treatment options for osteoporosis and cancer-related conditions.

The FDA designated 2 denosumab biosimilars, Stoboclo and Osenvelt (denosumab-bmwo; Celltrion USA), as interchangeable biosimilars to their respective reference products, Prolia and Xgeva (Amgen), for all approved indications effective as of October 29, 2025.1 Along with Conexxence and Bomyntra (denosumab-bnht; Fresenius Kabi), this is the second pair of denosumab biosimilars to recently receive this status.2

Initially approved on March 3, 2025, Stoboclo and Osenvelt are receptor activator of NF-κb ligand (RANKL) inhibitors, referencing Prolia and Xgeva, respectively. Like its reference product, Stoboclo is indicated to increase bone mass for several categories of patients[1,3]:

Postmenopausal women with osteoporosis at high risk for fracture.

Men with osteoporosis at high risk for fracture, or men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer.

Glucocorticoid-induced osteoporosis in men and women who are at high risk of bone fracture.

Women who are at high risk of fracture and are receiving an adjuvant aromatase inhibitor therapy for breast cancer.

Osenvelt is indicated to perform several functions1:

To prevent skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

To treat 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.

To treat hypercalcemia of malignancy refractory to bisphosphonate therapy.

According to a news release from the manufacturer, the FDA-granted interchangeability designation allows the biosimilars to be substituted at the pharmacy for their reference products without consulting the prescriber; however, this is subject to state-specific laws. The interchangeability designations for

Stoboclo and Osenvelt were supported by comprehensive evidence, including clinical findings from phase 3 trials evaluating the safety, efficacy, pharmacodynamics, pharmacokinetics, and immunogenicity of the denosumab biosimilars relative to their reference products when treating postmenopausal women with osteoporosis.[1,4]

Study findings demonstrated that, for primary efficacy and pharmacodynamic end points, CT-P41 was equivalent to denosumab in women with postmenopausal osteoporosis. The 18-month, double-blind, randomized, active-controlled phase 3 study (NCT04757376) consisted of 2 treatment periods. In the first treatment period, 479 patients were randomly assigned to receive either 60 mg of subcutaneous CT-P41 or denosumab. At week 52, those who had received the biosimilar continued treatment, whereas those who received denosumab were randomly reassigned to continue the reference product or switch to the biosimilar.[4,5]

Equivalence was demonstrated for CT-P41 and denosumab with respect to primary efficacy (LS mean difference: –0.139 [95% CI –0.826, 0.548] in the full analysis set; –0.280 [95% CI –0.973, 0.414] in the per-protocol set) and pharmacodynamics (geometric LS mean ratio: 94.94 [95% CI 90.75, 99.32]) end points. The study authors wrote that secondary efficacy, pharmacodynamics, pharmacokinetics, and safety results were comparable among all groups up to week 78, including after transitioning from reference denosumab to the biosimilar.[4]

"Today's [interchangeability] designations reinforce confidence in Stoboclo and Osenvel among physicians and pharmacists, facilitating a more seamless switch from the reference products to our denosumab biosimilars," Thomas Nusbickel, chief commercial officer at Celltrion USA, said in a news release. "Building on our strong heritage in biosimilars, Celltrion remains committed to offering more affordable and much-needed treatment options to patients living with skeletal diseases, creating greater potential to deliver savings to patients and the US health care system."[1]

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