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European Commission approves Biocon Biologics' Denosumab biosimilars

03 July 2025 | News

The two biosimilars of Denosumab have comparable quality, safety



Bengaluru-based Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd., has announced that the European Commission (EC) has granted marketing authorisation in the European Union (EU) for the biosimilars Denosumab, Vevzuo® and Evfraxy®.

Vevzuo® is approved for the prevention of bone complications in adults with advanced cancers with bone involvement, as well as for the treatment of adults and adolescents with mature bone structure with giant cell tumours (GCTs) of the bone.

Evfraxy® is approved for the treatment of osteoporosis in postmenopausal men and women, hormonal ablation in men with prostate cancer at increased risk of fractures, and for the treatment of bone loss associated with prolonged systemic glucocorticoid therapy.

Clinical data have demonstrated that the two biosimilars of Denosumab have comparable quality, safety and efficacy to the reference medicine.

This marketing authorisation follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on 25 April 2025.

Shreehas Tambe, CEO and Managing Director of Biocon Biologics Ltd., said: *"The approval of Vevzuo and Evfraxy in Europe underscores our strong scientific expertise and commitment to expanding patient access to essential medicines, including in new therapeutic areas such as bone health. In the last 18 months, we have successfully obtained regulatory approvals for three biosimilars in Europe and two in the United Kingdom. These Denosumab biosimilars represent another important milestone in our rapid expansion and support for healthcare systems in the region.*