

PRESS RELEASE

Advancing Bone Health: European Commission Approves Biocon Biologics' Denosumab Biosimilars

Bengaluru, Karnataka, India, July 3, 2025

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

Vevzuo® is authorised for the prevention of bone complications in adults with advanced cancer involving bone and the treatment of adults and skeletally mature adolescents with giant cell tumour (GCT) of bone.

Evfraxy® is authorised for the treatment of osteoporosis in men and postmenopausal women, the treatment of bone loss linked to hormone ablation in men with prostate cancer at increased risk of fractures or treatment of bone loss associated with long-term systemic glucocorticoid therapy in adults.

Clinical data showed that both Denosumab biosimilars have comparable quality, safety, and efficacy to the reference product¹.

The marketing authorisation follows a positive opinion issued by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) on April 25, 2025.

Shreehas Tambe, CEO & Managing Director, 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 to new therapeutic areas such as bone health. In the past 18 months, we have successfully secured regulatory approvals for three biosimilars in Europe and two in the UK. These Denosumab biosimilars mark another significant milestone in our rapid expansion, and support for healthcare systems in the region".

¹ Anna Strzelecka, Grzegorz Kania, Pawan Kumar Singh, Kuldeep Kumar, Binay Kumar Thakur, Ashwani Marwah, Sudipta Basu, Nitin Madhukar Chaudhari, Sarika S Deodhar, Elena Wolff-Holz, Sandeep Nilkanth Athalye, Subramanian Loganathan. A Randomized, Double-blind, Multicenter, Parallel-arm Phase 3 Study to Compare the Efficacy, Pharmacodynamics, Safety, and Immunogenicity between Bmab-1000 and Prolia in Postmenopausal Women with Osteoporosis. Poster presented at ACR Congress 2024

R. Eastell, E. Orwoll, F. Cosman, A. Strzelecka, G. Kania, R. Plebanski, A. Mansukhbhai Ranpura, K. Kumar, B. Kumar Thakur, A. Marwah, S. Basu, N. Madhukar Chaudhari, S. S Deodhar, E. Wolff-Holz, S. Loganathan. Equivalence Trial of Proposed Denosumab Biosimilar Bmab-1000 And Reference Denosumab In Postmenopausal Osteoporosis: The Devote Study. Poster presented at WCO-IEF-ESCEO 2025

Molecule Information:

Denosumab is a human monoclonal antibody that targets and binds a protein known as RANKL (Receptor Activator of Nuclear Factor Kappa-B Ligand). RANKL plays a crucial role in the formation, function, and survival of osteoclasts, which are the cells responsible for bone resorption. By blocking RANKL, denosumab effectively inhibits the breakdown of bone, leading to increased bone mass and strength.

Full indications:**Vevzuo® (denosumab biosimilar)**

Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone.
Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Evfraxy® (denosumab biosimilar)

Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral, and hip fractures.
Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures.
Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.

Epidemiology:

Osteoporosis is a health condition that weakens bones, making them fragile and more likely to break. It develops slowly over several years and is often only diagnosed when a fall or sudden impact causes a bone to fracture.² Across Europe, 32 million individuals aged 50+ were estimated to have osteoporosis in 2019, 25.5 million of which were women.³ According to the Royal Osteoporosis Society in the UK, one in five men over the age of 50 are likely to break a bone because of osteoporosis.⁴

Nearly all types of cancer can spread to the bone and cause pain and fractures. The number of new cancer cases in the EU reached 2.74 million in 2022.⁵

Giant cell tumour (GCT) is a type of benign (noncancerous) tumour that typically occurs in young adults between the ages of 20 and 40.⁶ They can be locally aggressive, meaning that they can grow

² <https://www.nhsinform.scot/illnesses-and-conditions/muscle-bone-and-joints/conditions-that-can-affect-multiple-parts-of-the-body/osteoporosis/#:~:text=Osteoporosis%20is%20a%20condition%20where,bone%20to%20fracture%20or%20break.>

³ [https://www.osteoporosis.foundation/facts-statistics/epidemiology-of-osteoporosis-and-fragility-fractures#:~:text=Across%20Europe%20in%202019%20\(European,aged%20%2B50\)%%20%5B7%5D](https://www.osteoporosis.foundation/facts-statistics/epidemiology-of-osteoporosis-and-fragility-fractures#:~:text=Across%20Europe%20in%202019%20(European,aged%20%2B50)%%20%5B7%5D)

⁴ <https://theros.org.uk/information-and-support/osteoporosis/osteoporosis-in-men/>

⁵ https://ecis.jrc.ec.europa.eu/sites/default/files/2024-01/jrc_CancerEstimates2022_factsheet.pdf

⁶ <https://orthoinfo.aaos.org/en/diseases--conditions/giant-cell-tumor-of-bone/>

quickly and destroy surrounding bone and soft tissue.⁷ GCTs represent 3–5% of primary bone tumours in the United States and Europe.⁸

About Biocon Biologics Limited:

Biocon Biologics Limited, a subsidiary of Biocon Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve over 5.8 million patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world-class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

Biocon Biologics has commercialized nine biosimilars from its portfolio which are addressing the patients' needs in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, bone health and other non-communicable diseases. The Company has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). **Website:** www.bioconbiologics.com; **Follow us on X** (formerly Twitter): @BioconBiologics and **LinkedIn:** [Biocon Biologics](#) for company updates. For FY24 Integrated Annual Report of Biocon Biologics [click here](#)

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development. **Website:** www.biocon.com; Follow-us on X (formerly Twitter) [@bioconlimited](#) and **LinkedIn:** [Biocon](#) for company updates.

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⁷ <https://www.bcrf.org.uk/information/information-by-type/giant-cell-tumor/>

⁸ <https://www.sciencedirect.com/science/article/pii/S2405844024069214#:~:text=Epidemiology,reportedly%20higher%20in%20Asian%20populations>