

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

Biocon Biologics Receives MHRA UK Approval for Vevzuo® and Evfraxy®, Denosumab Biosimilars

Bengaluru, Karnataka, India, July 7, 2025

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd., today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorisations in the United Kingdom (UK) for Vevzuo® and Evfraxy®, biosimilars of Denosumab.

Vevzuo® is authorized for the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone. Vevzuo is also authorized for the 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® is authorized for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women this significantly reduces the risk of vertebral, non-vertebral, and hip fractures. Furthermore, Evfraxy® is authorized for the 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, this significantly reduces the risk of vertebral fractures. Evfraxy® is also authorized for the treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.

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

In Europe, the European Commission (EC) recently granted marketing authorisation for Biocon Biologics Denosumab biosimilars, allowing their commercialization in all European Union (EU) member states and the European Economic Area (EEA).

– Company Spokesperson

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