

**Biocon Limited**

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CIN : L24234KA1978PLC003417

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BIO/SECL/TG/2025-26/125

December 02, 2025

To The Manager, BSE Limited Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, National Stock Exchange of India Limited Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code - 532523	Scrip Symbol - BIOCON

Dear Sir/ Madam,

Subject: Press Release

Please find enclosed the press release titled “**Biocon Biologics Secures Market Entry Date for Denosumab Biosimilars in Europe and Rest of the World®**”.

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

Rajesh U. Shanoy
Company Secretary and Compliance Officer
M. No.: ACS 16328

Encl: Press Release

PRESS RELEASE

Biocon Biologics Secures Market Entry Date for Denosumab Biosimilars in Europe and Rest of the World

BENGALURU, India: December 2, 2025

Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE: 532523, NSE: BIOCON), today announced a settlement agreement with Amgen Inc. that clears the path for the commercialization of its Denosumab biosimilars in Europe and the rest of the world.

The agreement allows Biocon Biologics to commercialize both its Denosumab biosimilars (Vevzuo® and Evfraxy®) in Europe starting December 2, 2025. The other terms of the settlement remain confidential.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics, said, *“This settlement sets the stage for Biocon Biologics to bring our Denosumab biosimilars, Vevzuo® and Evfraxy®, to patients across Europe and key international markets. This follows our settlement in the U.S. in October and further broadens our reach across the world in the oncology and bone health therapeutic areas, as we work with healthcare systems to expand access to affordable biologics globally.”*

The [European Commission \(EC\)](#) had approved Vevzuo and Evfraxy in July 2025.

Biocon Biologics had secured a market entry date for its Denosumab biosimilars Bosaya™ (denosumab-kyqq) and Aukelso™ (denosumab-kyqq) [for the United States previously](#).

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.¹

Across Europe, 32 million individuals aged 50+ were estimated to have osteoporosis in 2019, 25.5 million of which were women.²

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.³

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 2022.⁴

Giant cell tumour (GCT) is a type of benign (noncancerous) tumour that typically occurs in young adults between the ages of 20 and 40.⁵ They can be locally aggressive, meaning that they can grow quickly and destroy surrounding bone and soft tissue.⁶ GCTs represent 3–5% of primary bone tumours in the United States and Europe.⁷

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 6.0 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 10 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). The meaningful progress on ESG parameters has been recognized with the Company's inclusion in the S&P Global Sustainability Yearbook in 2025. Website: www.bioconbiologics.com; Follow us on X (formerly Twitter): @BioconBiologics and LinkedIn: [Biocon Biologics](#) for company updates.

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](https://twitter.com/bioconlimited) and **LinkedIn:** [Biocon](https://www.linkedin.com/company/biocon) for company updates.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

For More Information: Biocon Biologics	
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¹ [https://www.nhsinform.scot/illnesses-and-conditions/muscle-bone-and-joints/conditions-that-can-affect-multiple-parts-of-the-](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.)

[body/osteoporosis/#:~:text=Osteoporosis%20is%20a%20condition%20where,bone%20to%20fracture%20or%20break.](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.)

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

³ <https://theros.org.uk/information-and-support/osteoporosis/osteoporosis-in-men/>

⁴ https://ecis.jrc.ec.europa.eu/sites/default/files/2024-01/jrc_CancerEstimates2022_factsheet.pdf

⁵ <https://orthoinfo.aaos.org/en/diseases-conditions/giant-cell-tumor-of-bone/>

⁶ <https://www.bcrf.org.uk/information/information-by-type/giant-cell-tumor/>

⁷ <https://www.sciencedirect.com/science/article/pii/S2405844024069214>