

Biocon Receives Health Canada Approval of Bosaya™ (Denosumab) and Vevzuo™ (Denosumab), Biosimilars to Prolia® and Xgeva®

- Bosaya™ and Vevzuo™ (both denosumab products) now approved by Health Canada
- Potential benefit to more than 2 million adults with osteoporosis and hundreds of patients annually with bone metastasis, a common complication of advanced cancer

TORONTO, Ontario, Canada and BENGALURU, Karnataka, India: April 21, 2026

Biocon Limited (BSE: 532523; NSE: BIOCON), an innovation-led global biopharmaceutical company, is pleased to announce that Health Canada has granted a Notice of Compliance (NOC) for **Bosaya™ (denosumab)**, a biosimilar to Prolia®, and **Vezuo™ (denosumab)**, a biosimilar to Xgeva®, on April 3, 2026. Both biosimilars were approved in the most common presentations: **BOSAYA**, as a 60 mg/mL injection for subcutaneous use in a prefilled syringe; and **VEVZUO**, as a 120 mg/1.7 mL (70 mg/mL) injection for subcutaneous use in a single-dose vial.

Denosumab products play a key role in bone health by increasing bone mass and treating osteoporosis, as well as bone complications associated with cancer.

Shreehas Tambe, CEO & Managing Director, Biocon Ltd., said, “*Health Canada’s approval of BOSAYA and VEVZUO marks another important milestone for Biocon as we continue to expand access to high-quality biosimilars in key global markets. This approval reflects our strong scientific and regulatory capabilities and reinforces our commitment to patients living with osteoporosis and cancer-related bone conditions, while further strengthening our portfolio of affordable biologic therapies across immunology and oncology.*”

BOSAYA is approved for the treatment:

- of postmenopausal women with osteoporosis at high risk for fracture
- to increase bone mass in men with osteoporosis at high risk for fracture
- to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture
- to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy
- to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy and fracture who are starting or have recently started long term glucocorticoid therapy

VEVZUO is approved for the treatment of:

- reducing the risk of developing skeletal-related events in patients with multiple myeloma and in patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer, and other solid tumours
- 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
- treatment of hypercalcemia of malignancy that is refractory to intravenous bisphosphonate

The approval is based on a comprehensive package of analytical, nonclinical, and clinical data, demonstrating that BOSAYA and VEVZUO are highly similar to PROLIA and XGEVA, respectively, with no clinically meaningful differences in quality, safety, or efficacy.

About BOSAYA and VEVZUO:

Denosumab is a human monoclonal antibody that targets and binds to Receptor Activator of Nuclear Factor Kappa-B Ligand (RANKL). RANKL is essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. By blocking RANKL, denosumab reduces bone breakdown, increasing bone mass and strength.

About BOSAYA (denosumab)

Warnings and Precautions:

- **Hypocalcemia:** must be corrected by adequate intake of calcium and vitamin D prior to initiating therapy with BOSAYA. Other disorders affecting mineral metabolism (such as vitamin D deficiency) should be treated.
- The safety and efficacy of denosumab have not been studied in patients with hepatic impairment.
- **Hypersensitivity:** Clinically significant hypersensitivity reactions including anaphylaxis have been reported with denosumab. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria.
- **Infections:** in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported for the following:
 - skin infections leading to hospitalization predominantly cellulitis
 - infections of the abdomen, urinary tract, and ear
 - endocarditis
- Monitoring of calcium is recommended before each dose.
- Osteonecrosis of the jaw (ONJ) may increase with duration of exposure to BOSAYA.
- Atypical femoral fractures have been reported in patients receiving denosumab.
- Multiple vertebral fractures (MVF) may occur following discontinuation of treatment with BOSAYA, particularly in patients with a history of vertebral fracture.
- Treatment with denosumab resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry.
- **Skin:** Women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema, and rashes occurred at a significantly higher rate in the denosumab
- BOSAYA is not indicated for use in pediatric patients.
- There have been no studies of denosumab in pregnant women.
- BOSAYA is not recommended for use in nursing women

About VEVZUO (denosumab)

Warnings and Precautions:

- **Hypocalcemia:** VEVZUO can cause severe symptomatic hypocalcemia and fatal cases. Signs and symptoms of severe hypocalcemia may include, for example, altered mental status, tetany, seizures and QTc prolongation.
- Hypercalcemia following treatment discontinuation in patients with giant cell tumour of bone and in patients with growing skeletons.
- No clinical studies have been conducted to evaluate the effect of hepatic impairment
- Clinically significant hypersensitivity reactions including anaphylaxis have been reported with denosumab. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria.

- Monitor calcium levels, (i) prior to the initial dose of VEVZUO, (ii) within two weeks after the initial dose, and (iii) if suspected symptoms of hypocalcemia occur. Additional monitoring should be considered during therapy in patients with risk factors for hypocalcemia
- ONJ has been reported in patients treated with denosumab or bisphosphonates, another class of anti-resorptive agents.
- Atypical femoral fracture has been reported with denosumab.
- Multiple vertebral fractures (MVF), not due to bone metastases, may occur following discontinuation of treatment with VEVZUO, particularly in patients with risk factors such as osteoporosis or prior fractures.
- There was a greater risk of developing hypocalcemia with increasing degree of renal impairment, and in the absence of, or inadequate calcium supplementation.
- An imbalance of skin infections leading to hospitalization was reported, predominantly cellulitis
- The safety and efficacy of VEVZUO in pregnant women have not been established.
- It is not known whether VEVZUO is excreted into human milk.

Please refer to full Product Monograph for BOSAYA and VEVZUO for more information.

To report SUSPECTED ADVERSE REACTIONS, contact Biocon at 1-833-986-1468.

About Biocon Limited

Biocon Limited (BSE: 532523, NSE: BIOCON) is a global biopharmaceutical company driven by its purpose to provide affordable, life-changing medicines to patients worldwide. Headquartered in Bengaluru, India, Biocon addresses some of the world's most pressing healthcare challenges across chronic and non-communicable diseases by offering both biosimilars and generics at scale across geographies. Through this diversified portfolio, Biocon focuses on areas of high unmet need, spanning key therapy areas including diabetes, oncology, obesity, cardiovascular diseases, immunology, ophthalmology, and bone health. The Company has pioneered several industry firsts that have helped shape the global biosimilars landscape. To date, the company has commercialized 12 biosimilar products and 30+ generic formulations globally. It has robust research and development pipeline of 20+ biosimilar assets, as well as GLP-1 peptides and other complex generics. With an integrated lab-to-patient model, Biocon brings together research and development, manufacturing, and commercial capabilities to ensure reliable and scalable supply of medicines. The company operates in more than 120 countries, supported by seven manufacturing sites, three R&D sites, 18 offices worldwide, and a workforce of over 9,500 employees. Biocon has been included in the S&P Global Sustainability Yearbook 2026 for the fourth consecutive year, underscoring its commitment to sustainable and responsible growth. Website: www.biocon.com Follow us on X: [@bioconlimited](https://twitter.com/bioconlimited) LinkedIn: [Biocon](https://www.linkedin.com/company/biocon)

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.

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