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BIO/SECL/TG/2026-27/01

April 07, 2026

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 Announces U.S. Commercial Launch of Bosaya™ and Aukelso™, Denosumab Biosimilars".**

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
Digitally signed by RAJESH U SHANOY
Date: 2026.04.07 15:58:17 +05'30'

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

Encl: Press Release

PRESS RELEASE

Biocon Announces U.S. Commercial Launch of Bosaya™ and Aukelso™, Denosumab Biosimilars

- Bosaya™ and Aukelso™ (both denosumab-kyqq products) now available in the United States, following U.S. FDA approval in September 2025 with an interchangeable designation
- Potential benefit to the estimated 10 million adults with osteoporosis and over 330,000 patients annually with bone metastasis, a common complication of advanced cancer

BENGALURU, India and BRIDGEWATER, N.J., United States: April 7, 2026

Biocon Limited (BSE: 532523; NSE: BIOCON), an innovation-led global biopharmaceutical company, today announced the commercial launch of **Bosaya™ (denosumab-kyqq)** and **Aukelso™ (denosumab-kyqq)** in the United States. Bosaya™ (biosimilar to *Prolia®*) and Aukelso™ (biosimilar to *Xgeva®*) are now available by prescription nationwide through specialty pharmacies and healthcare providers. Both products have been previously approved and granted **interchangeable designation** by the U.S. Food and Drug Administration in September 2025, allowing substitution at the pharmacy level in accordance with state laws.

Shreehas Tambe, CEO & Managing Director, Biocon Limited, said, "*The U.S. introduction of Bosaya™ and Aukelso™ marks a strategic expansion of our biosimilars portfolio, building on our established leadership in oncology and immunology. These therapies broaden access to high-quality, affordable treatment options for patients living with serious bone conditions. This milestone underscores Biocon's strength as a portfolio development engine and our focus on building the world's most scalable access platform—advancing life-changing medicines for patients and health systems across the United States and around the world.*"

Denosumab products play a critical role in bone health, treating osteoporosis and bone complications associated with cancer. In 2024, denosumab products generated approximately **$5 billion in U.S. sales**, reflecting the growing need for accessible treatment options.

Both biosimilars will be available in the most common presentations:

- **Bosaya™ (biosimilar to Prolia®)**: 60 mg/mL injection for subcutaneous use in a prefilled syringe.
- **Aukelso™ (biosimilar to Xgeva®)**: 120 mg/1.7 mL (70 mg/mL) injection for subcutaneous use in a single-dose vial.

Epidemiology:
Osteoporosis is a chronic disease that weakens bones, making them fragile and more prone to fracture. In the United States, approximately 10 million adults over age 50 are estimated to have osteoporosis, with another 44 million at risk due to low bone density.[3,4] One in two women and up to one in four men over age 50 will break a bone in their lifetime due to osteoporosis.[5]

Bone metastases are a common complication of advanced cancer, affecting more than 330,000 patients annually in the United States.[6] Skeletal complications can significantly impair quality of life and increase healthcare burden.[7]

Giant cell tumor of bone (GCTB) is a rare, locally aggressive benign tumor that primarily affects young adults. While noncancerous, it can cause severe pain, fractures, and disability.

About BOSAYA[1] and AUKELSO[2]:
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-kyqq)

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE
See full prescribing information for complete boxed warning.

- **Patients with advanced chronic kidney disease are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.**
- **The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia.**

Prior to initiating BOSAYA in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with BOSAYA in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Warnings and Precautions:

- Pre-existing hypocalcemia must be corrected before initiating BOSAYA. May worsen, especially in patients with renal impairment. Adequately supplement all patients with calcium and vitamin D. Concomitant use of calcimimetic drugs may also worsen hypocalcemia risk. Evaluate for presence of chronic kidney disease mineral-bone disorder. Monitor serum calcium.
- Patients receiving BOSAYA should not receive other denosumab products concomitantly.
- Hypersensitivity including anaphylactic reactions may occur. Discontinue permanently if a clinically significant reaction occurs.
- Osteonecrosis of the jaw has been reported with denosumab products. Monitor for symptoms.
- Atypical femoral fractures: Have been reported. Evaluate patients with thigh or groin pain to rule out a femoral fracture.
- Multiple vertebral fractures have been reported following treatment discontinuation. Patients should be transitioned to another antiresorptive agent if BOSAYA is discontinued.
- Serious infections including skin infections may occur, including those leading to hospitalization. Advise patients to seek prompt medical attention if they develop signs or symptoms of infection, including cellulitis.
- Dermatologic reactions such as, dermatitis, rashes, and eczema have been reported. Consider discontinuing BOSAYA if severe symptoms develop.
- Severe bone, joint, muscle pain may occur. Discontinue use if severe symptoms develop.
- Significant suppression of bone turnover has been demonstrated. Monitor for consequences of bone over-suppression.

Adverse reactions:

- Postmenopausal osteoporosis: Most common adverse reactions (> 5% and more common than placebo) were: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials.
- Male osteoporosis: Most common adverse reactions (> 5% and more common than placebo) were: back pain, arthralgia, and nasopharyngitis.
- Glucocorticoid-induced osteoporosis: Most common adverse reactions (> 3% and more common than active-control group) were: back pain, hypertension, bronchitis, and headache.

- Bone loss due to hormone ablation for cancer: Most common adverse reactions (≥ 10% and more common than placebo) were: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

Use in Specific Populations:

- Pregnant women and females of reproductive potential: Denosumab products may cause fetal harm when administered to pregnant women. Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of BOSAYA.
- Pediatric patients: BOSAYA is not approved for use in pediatric patients.
- Renal impairment: No dose adjustment is necessary in patients with renal impairment. Patients with advanced chronic kidney disease (eGFR<30 mL/min/1.73 m2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia. The presence of underlying chronic kidney disease-mineral bone disorder markedly increases the risk of hypocalcemia.

About AUKELSO (denosumab-kyqq)

Warnings and Precautions:

- Patients receiving AUKELSO should not receive other denosumab products concomitantly.
- Hypersensitivity reactions including anaphylaxis may occur. Discontinue permanently if a clinically significant reaction occurs.
- Denosumab products can cause severe symptomatic hypocalcemia. Fatal cases have been reported with denosumab products use. Correct hypocalcemia prior to initiating AUKELSO. Monitor calcium levels during therapy, especially in the first weeks of initiating therapy, and adequately supplement all patients with calcium and vitamin D.
- Osteonecrosis of the jaw (ONJ) has been reported in patients receiving denosumab products. Perform an oral examination prior to starting AUKELSO. Monitor for symptoms. Avoid invasive dental procedures during treatment with AUKELSO.
- Evaluate patients with thigh or groin pain to rule out a femoral fracture.
- Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone and in Patients with Growing Skeletons, patients should be monitored for signs and symptoms of hypercalcemia, and manage as clinically appropriate.
- Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation, when AUKELSO treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.
- Embryo-Fetal Toxicity can cause fetal harm. Advise females of reproductive potential of potential risk to the fetus and to use effective contraception.

Adverse Reactions:

- Bone Metastasis from Solid Tumors: Most common adverse reactions (≥ 25%) were fatigue/asthenia, hypophosphatemia, and nausea.
- Multiple Myeloma: Most common adverse reactions (≥ 10%) were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- Giant Cell Tumor of Bone: Most common adverse reactions (≥ 10%) were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- Hypercalcemia of Malignancy: Most common adverse reactions (> 20%) were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Use in Specific Populations:

- Pediatric patients: Recommended only for treatment of skeletally mature adolescents with giant cell tumor of bone.
- Renal impairment: Patients with creatinine clearance less than 30 mL/min or receiving dialysis are at risk for hypocalcemia. Adequately supplement with calcium and vitamin D.

Please refer to the full Patient Information for detailed safety information. To report SUSPECTED ADVERSE REACTIONS, contact Biocon at 1-833-986-1468.

[1] BOSAYA. Prescribing information. Biocon Biologics Inc; 2025.
[2] AUKELSO. Prescribing information. Biocon Biologics Inc; 2025.
[3] Bone Health and Osteoporosis Foundation. "Osteoporosis Fast Facts." Accessed: September 14, 2025. https://www.bonehealthandosteoporosis.org/wp-content/uploads/Osteoporosis-Fast-Facts-2.pdf
[4] American Medical Association. "What doctors wish patients knew about osteoporosis." Accessed: September 14, 2025. Published: May 3, 2024. https://www.ama-assn.org/public-health/prevention-wellness/what-doctors-wish-patients-knew-about-osteoporosis
[5] Hernandez RK, Adhia A, Wade SW, O'Connor E, Arellano J, Francis K, Alvrtsyan H, Million RP, Liede A. Prevalence of bone metastases and bone-targeting agent use among solid tumor patients in the United States. Clin Epidemiol. 2015 Jul 17;7:335-45.
[6] Moffitt Cancer Center. "Bone Metastasis." Accessed: September 14, 2025. https://www.moffitt.org/cancers/bone-metastasis/
[7] American Cancer Center. "Bone Metastases." Accessed: September 14, 2025. https://www.cancer.org/cancer/managing-cancer/advanced-cancer/bone-metastases.html

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 LinkedIn: 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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