PRESS RELEASE

Biocon Biologics Receives U.S. Food and Drug Administration Approval for Bosaya™ and Aukelso™, Denosumab Biosimilars

BENGALURU, India and BRIDGEWATER, N.J., United States: September 17, 2025

Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. (BSE: 532523, NSE: BIOCON), today announced that the U.S. Food and Drug Administration (FDA) has approved Bosaya™ (denosumab-kyqq) 60 mg/mL injection for subcutaneous use in a single dose prefilled syringe (PFS), and Aukelso™ (denosumab-kyqq) 120 mg/1.7 mL (70 mg/mL) injection for subcutaneous use in a single-dose vial, biosimilars of Prolia® and Xgeva® respectively. In addition, the U.S. FDA granted provisional interchangeability designation for both BOSAYA and AUKELSO.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics, *said, "The FDA's approval of Bosaya™ and Aukelso™ is a significant milestone in our mission to expand access to critical biologic therapies. With Bosaya™, we are proud to offer a more affordable treatment option for patients with osteoporosis, and with Aukelso™, we are further expanding our oncology care portfolio. This achievement underscores our scientific and regulatory capabilities and reinforces our commitment to delivering high-quality biosimilars that support sustainable healthcare systems and improve patient outcomes."*

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, glucocorticoid-induced osteoporosis in men and women at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

AUKELSO is approved for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, to treat adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and to treat hypercalcemia of malignancy refractory to bisphosphonate therapy.

Clinical data showed that both biosimilars demonstrated comparable quality, safety, and efficacy to the reference product. BOSAYA is approved with the same Risk Evaluation and Mitigation Strategy (REMS) plan as PROLIA to likewise inform healthcare providers and patients of the risks of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), including dialysis-dependent patients, associated with BOSAYA.

According to IQVIA National Sales Perspectives Data, denosumab had nearly $5 billion in U.S. sales for the period ending December 2024, with PROLIA achieving $3.3 billion and XGEVA generating $1.6 billion.

Epidemiology:
Osteoporosis is a chronic disease that weakens bones, making them fragile and more prone to fracture. In the U.S., approximately 10 million adults over age 50 are estimated to have osteoporosis, with another 44 million at risk due to low bone density.[1,2] One in two women and up to one in four men over age 50 will break a bone in their lifetime due to osteoporosis.[3]

Bone metastases are a common complication of advanced cancer, affecting more than 330,000 patients annually in the United States.[4] Skeletal complications can significantly impair quality of life and increase healthcare burden.[5]

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 and AUKELSO:
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 m^2), 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 Biologics at 1-833-986-1468.

[1] Bone Health and Osteoporosis Foundation. "Osteoporosis Fast Facts." Accessed: September 14, 2025. https://www.bonehealthandosteoporosis.org/wp-content/uploads/Osteoporosis-Fast-Facts-2.pdf
[2] 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
[3] 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.
[4] Moffitt Cancer Center. "Bone Metastasis." Accessed: September 14, 2025. https://www.moffitt.org/cancers/bone-metastasis/

[5] American Cancer Center. "Bone Metastases." Accessed: September 14, 2025. https://www.cancer.org/cancer/managing-cancer/advanced-cancer/bone-metastases.html

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 and **LinkedIn**: 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.

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