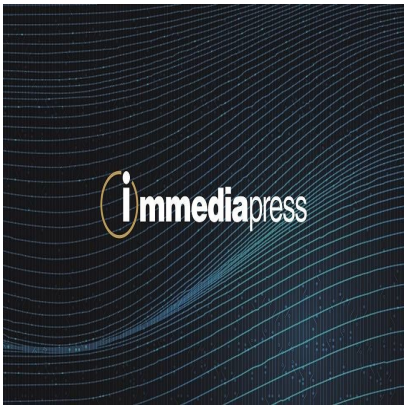


Bioconâ??s Pertuzumab Receives Marketing Authorization in EU, First Biosimilar Authorized Under EMAâ??s New Tailored Clinical Approach

Descrizione

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COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

BENGALURU, India, Nov. 18, 2026 /PRNewswire/ â?? Biocon Limited (BSE: 532523; NSE: BIOCON), an innovation-led global biopharmaceutical company, today announced that the European Commission (EC) has granted marketing authorization for PebrilzoÂ®, its biosimilar pertuzumab, for the treatment of HER2-positive breast cancer across multiple disease stages in the European Union (EU).

Bioconâ??s pertuzumab biosimilar is the first biosimilar to receive EC marketing authorisation under the European Medicines Agencyâ??s (EMA) new tailored clinical approach. This milestone follows its positive CHMP opinion on September 17, 2026.1

Shreehas Tambe, CEO & Managing Director, Biocon, said: â??The European Commissionâ??s approval of PebrilzoÂ®, our pertuzumab biosimilar, the first under its new tailored clinical pathway, marks a significant regulatory milestone for Biocon. With this approval, pertuzumab becomes our fifth oncology biosimilar approved in both Europe and the United States, strengthening our global oncology portfolio and reinforcing our commitment to expanding access to high-quality, affordable biologic therapies for patients with HER2-positive breast cancer.â?•

Molecule Information:

Bioconâ??s pertuzumab biosimilar, approved as a 420 mg concentrate for solution for infusion, is a biosimilar medicinal product and the active substance is pertuzumab, a monoclonal antibody that binds with high affinity and specificity to the human epidermal growth factor receptor 2 (HER2), inhibiting the proliferation of tumour cells that overexpress HER2.

Bioconâ??s pertuzumab biosimilar is indicated for use in combination with trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2â??positive, locally advanced,

inflammatory, or early-stage breast cancer at high risk of recurrence, as well as in the adjuvant treatment of adult patients with HER2â??positive early breast cancer at high risk of recurrence.

In addition, it is indicated for use in combination with trastuzumab and docetaxel in adult patients with HER2 positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.Extensive orthogonal, state-of-the-art structural and functional analytical characterisation, together with comparative clinical pharmacokinetic data, demonstrated that Bioconâ??s pertuzumab biosimilar is highly similar to the reference product, with no clinically meaningful differences in quality, safety, or efficacy.

Biocon in Oncology

Biocon has a strong and growing commitment to oncology, with a portfolio spanning multiple areas of cancer care, including solid tumors such as breast cancer, as well as supportive care addressing chemotherapy-induced neutropenia. This commitment also extends to bone health, with therapies addressing osteoporosis, treatment-related bone loss and skeletal complications associated with advanced cancers2. Biosimilar pertuzumab further strengthens the companyâ??s portfolio and its ability to support patients across different stages of the cancer care journey and diverse healthcare systems.

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Epidemiology:

Breast cancer remains the most commonly diagnosed cancer among women in Europe. According to 2024 estimates from the European Cancer Information System (ECIS), it is the leading cancer diagnosis among women across Europe3. Approximately 15â??20% of invasive breast cancers are characterised by HER2 overexpression or amplification4.Despite significant advances in HER2-targeted treatment, the burden of breast cancer underscores the importance of broad and sustainable access to high-quality treatment options across European healthcare systems.2,3

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 worldâ??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

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1European Medicines Agency (EMA), â??Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP), 14-17 September 2026â?•. Available at: https://www.ema.europa.eu/en/news/meeting-highlights-committee-medicinal-products-human-use-chmp-14-17-september-2026
2Li K, Qian Y, Cao Y. Risk of osteoporosis and fracture among patients with breast cancer: a systematic review and meta-analysis of cohort studies. Front Oncol. 2026 Aug 31;16:1905334. https://pmc.ncbi.nlm.nih.gov/articles/PMC13572274/
3European Cancer Information System (ECIS), European Commission Joint Research Centre. Female Breast Cancer in EU-27/EFTA Countries: Estimates for 2024. October 2026https://ecis.jrc.ec.europa.eu/sites/default/files/2026-10/2026-10_A4_Factsheet_breast-cancer_F.pdf
4Marra A. et al. Management of advanced-stage HER2+ breast cancer: current evidence and future perspectives. Nature Reviews Clinical Oncology. 2024;21:185â??202. The review reports HER2 overexpression or amplification in approximately 15â??20% of invasive breast cancers https://pmc.ncbi.nlm.nih.gov/articles/PMC12327481/

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