



Biocon's Pertuzumab Becomes First Biosimilar to Secure EMA CHMP Approval Recommendation Under New Tailored Clinical Approach

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

BENGALURU, India, Sept. 22, 2026 /PRNewswire/ - Biocon Biologics Limited, a wholly-owned subsidiary of Biocon Limited (BSE: 532523) (NSE: BIOCON), today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the granting of a marketing authorisation to its Pertuzumab biosimilar as 420 mg concentrate solution for infusion, under the brand name Pebrilzo®, for the treatment of HER2-positive breast cancer across multiple disease stages.

The positive opinion follows the review of the marketing authorization application submitted by Biocon Biologics Ireland Limited (formerly Biosimilar Collaborations Ireland Limited), an indirect wholly-owned subsidiary of Biocon Biologics Limited.

Shreehas Tambe, CEO & Managing Director, Biocon, said: "The positive CHMP opinion for our Pertuzumab biosimilar marks an important step toward expanding access to biologic therapies for patients with HER2-positive breast cancer in Europe. As the first monoclonal antibody biosimilar to receive a positive CHMP opinion under EMA's tailored clinical development approach, it reflects an important milestone in the evolution of biosimilar science and greater regulatory confidence on advanced analytical and clinical pharmacology evidence to establish biosimilarity."

The European Commission will now proceed with the final review of the application and issue its decision. Following a positive decision, the Summary of Product Characteristics (SmPC) will be available in all official European Union languages, while the European Public Assessment Report (EPAR) will be published on the EMA website in the weeks following the decision.

Until marketing authorisation is granted by the European Commission, the product is not authorised for use in the European Union.

About the Product:

Pebrilzo® 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.

It is indicated for use in combination with Trastuzumab and chemotherapy in the neoadjuvant treatment of adult patients with HER2-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 HER2-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 characterization, together with comparative clinical pharmacokinetic data, demonstrated that Pebrilzo®, a Pertuzumab biosimilar, is highly similar to the reference biologic, with no clinically meaningful differences in quality, safety, or efficacy.

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

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Data di creazione

Settembre 22, 2026

Autore

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