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November 16, 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 – 400 051
Scrip Code - 532523	**Scrip Symbol - BIOCON**

Dear Sir/ Madam,

Subject: Press Release

Please find enclosed the press release titled **"Biocon Gets U.S. FDA Approval for Pebrilzo™ (pertuzumab-qcay) Injection, a Biosimilar to Perjeta®, Expanding Its Oncology Portfolio".**

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 UMAKANT SHANOY
Digitally signed by RAJESH UMAKANT SHANOY
Date: 2026.11.16 08:26:55 +05'30'

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

Encl: Press Release

PRESS RELEASE

Biocon Gets U.S. FDA Approval for Pebrilzo™ (pertuzumab-qcay) Injection, a Biosimilar to Perjeta®, Expanding Its Oncology Portfolio

- Biocon's PEBRILZO approval represents an important step toward broadening treatment option for patients with HER2-positive breast cancer in the United States, subject to the anticipated commercial launch timeline
- PEBRILZO further strengthens Biocon's oncology portfolio, now totaling five biosimilar therapies for cancer in the United States

BENGALURU, India and BRIDGEWATER, N.J., United States: November 16, 2026

Biocon Limited (BSE: 532523; NSE: BIOCON), an innovation-led global biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved Pebrilzo™ (pertuzumab-qcay), a biosimilar of the reference product Perjeta® (pertuzumab). PEBRILZO is a monoclonal antibody used to treat HER2-positive breast cancer by blocking HER2 receptors on cancer cells. The FDA approval further strengthens Biocon's oncology portfolio.

Shreehas Tambe, CEO & Managing Director, Biocon Limited, said, *"The U.S. FDA approval of PEBRILZO, our biosimilar pertuzumab, marks another significant milestone in Biocon's journey to expand access to high-quality biosimilars. For patients diagnosed with HER2-positive breast cancer, the burden of the disease extends well beyond the physical challenges, often placing considerable financial strain on patients and their families. As our fifth oncology biosimilar to receive U.S. FDA approval, PEBRILZO strengthens our anti-cancer portfolio and advances our commitment to expanding access to high-quality, affordable biologic medicines."*

In September, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had given a positive opinion recommending the granting of a marketing authorization for Biocon's Pertuzumab biosimilar as 420 mg/14 mL concentrate solution for infusion, under the brand name Pebrilzo®, for the treatment of HER2-positive breast cancer across multiple disease stages in Europe.

Biocon also announced a global settlement and license agreement with Genentech securing the earliest licensed launch date for PEBRILZO in the United States in Q3 of calendar year 2028.

Biocon's Oncology Portfolio and Pipeline:
Biocon's oncology strategy combines an established portfolio with continued development across additional treatment approaches. PEBRILZO will join its robust portfolio of oncology therapies, which includes Ogivri® (trastuzumab-dkst), Jobevne® (bevacizumab-nwgd), Fulphila® (pegfilgrastim-jmdb), and Aukelso® (denosumab-kyqq). Building on this foundation, Biocon's growing oncology pipeline includes proposed biosimilars to trastuzumab/hyaluronidase, nivolumab and pembrolizumab, spanning HER2-directed therapy and immuno-oncology.

About HER2-Positive Breast Cancer:
HER2-positive breast cancer is a subtype of breast cancer characterized by HER2 protein overexpression and/or HER2 gene amplification, which drives aggressive tumor growth.

Approximately 320,000 women in the United States are expected to be diagnosed with breast cancer in 2026.[1] Of those diagnoses, about 20% will be HER2-positive breast cancer[2]. On a broader scale, 1 in 8 women are expected to be diagnosed with breast cancer during her lifetime, highlighting the ongoing need for treatment options in this area[3].

About PEBRILZO (pertuzumab-qcay)

The approval for PEBRILZO (pertuzumab-qcay) was based on a comprehensive package containing structural and functional analytical characterization, analytical similarity, and comparative clinical pharmacokinetic data, which confirmed that PEBRILZO is highly similar to the reference biologics, Perjeta® with no clinically meaningful differences in quality, safety, efficacy, and immunogenicity.

WARNING
LEFT VENTRICULAR DYSFUNCTION and EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction: PEBRILZO can cause subclinical and clinical cardiac failure manifesting as decreased LVEF and CHF. Evaluate cardiac function prior to and during treatment. Discontinue PEBRILZO treatment for a confirmed clinically significant decrease in left ventricular function.**
- **Embryo-fetal Toxicity: Exposure to PEBRILZO can cause embryo-fetal death and birth defects. Advise patients of these risks and the need for effective contraception.**

INDICATIONS

PEBRILZO is a HER2/neu receptor antagonist indicated for:

- **Metastatic Breast Cancer (MBC):** PEBRILZO is indicated for use in combination with trastuzumab and docetaxel for the treatment of adults with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- **Early Breast Cancer (EBC):** PEBRILZO is indicated for use in combination with trastuzumab and chemotherapy for:
    - the neoadjuvant treatment of adults with HER2-positive, locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
    - the adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence.

CONTRAINDICATIONS

PEBRILZO is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients.

WARNINGS AND PRECAUTIONS
Left Ventricular Dysfunction

- Pertuzumab can cause left ventricular dysfunction, including symptomatic heart failure. Decreases in LVEF have been reported with drugs that block HER2 activity, including PEBRILZO.
- Assess LVEF prior to initiation of PEBRILZO and at regular intervals during treatment to ensure that LVEF is within normal limits. If the LVEF declines and has not improved, or has declined further at the subsequent assessment, consider permanent discontinuation of PEBRILZO and trastuzumab.
- In the pertuzumab-treated patients with MBC in CLEOPATRA, left ventricular dysfunction occurred in 4% of patients and symptomatic left ventricular systolic dysfunction (LVSD) (congestive heart failure) occurred in 1% of patients. Patients who received prior anthracyclines

[1] Breast Cancer Facts & Stats 2026 - Incidence, Age, Survival, & More
[2] Female Breast Cancer Subtypes — Cancer Stat Facts
[3] Breast cancer statistics 2024 - Giaquinto - 2024 - CA: A Cancer Journal for Clinicians - Wiley Online Library

or prior radiotherapy to the chest area may be at higher risk of decreased LVEF or left ventricular dysfunction.

- In patients receiving pertuzumab as a neoadjuvant treatment in combination with trastuzumab and docetaxel in NeoSphere, LVEF decline > 10% and a drop to < 50% occurred in 8% of patients and left ventricular dysfunction occurred in 3% of patients. LVEF recovered to ≥ 50% in all these patients.
- In patients receiving neoadjuvant pertuzumab in TRYPHAENA, LVEF decline > 10% and a drop to < 50% occurred in 7% of patients treated with pertuzumab plus trastuzumab and FEC followed by pertuzumab plus trastuzumab and docetaxel, 16% of patients treated with pertuzumab plus trastuzumab and docetaxel following FEC, and 11% of patients treated with pertuzumab in combination with TCH. Left ventricular dysfunction occurred in 6% of patients treated with pertuzumab plus trastuzumab and FEC followed by pertuzumab plus trastuzumab and docetaxel, 4% of patients treated with pertuzumab plus trastuzumab and docetaxel following FEC, and 3% of patients treated with pertuzumab in combination with TCH. Symptomatic LVSD occurred in 4% of patients treated with pertuzumab plus trastuzumab and docetaxel following FEC, 1% of patients treated with pertuzumab in combination with TCH, and none of the patients treated with pertuzumab plus trastuzumab and FEC followed by pertuzumab plus trastuzumab and docetaxel. LVEF recovered to ≥ 50% in all but one patient.
- In patients receiving neoadjuvant pertuzumab in BERENICE, in the neoadjuvant period, LVEF decline ≥ 10% and a drop to < 50% as measured by ECHO/MUGA assessment occurred in 7% of patients treated with pertuzumab plus trastuzumab and paclitaxel following ddAC, and 2% of patients treated with pertuzumab plus trastuzumab and docetaxel following FEC. Ejection fraction decreased (asymptomatic LVD) occurred in 7% of patients treated with pertuzumab plus trastuzumab and paclitaxel following ddAC and 4% of the patients treated with pertuzumab plus trastuzumab and docetaxel following FEC in the neoadjuvant period. Symptomatic LVSD (NYHA Class III/IV Congestive Heart Failure) occurred in 2% of patients treated with pertuzumab plus trastuzumab and paclitaxel following ddAC and none of the patients treated with pertuzumab plus trastuzumab and docetaxel following FEC in the neoadjuvant period.
- In patients receiving adjuvant pertuzumab in APHINITY, the incidence of symptomatic heart failure (NYHA Class III/IV) with a LVEF decline ≥ 10% and a drop to < 50% was 0.6%. Of the patients who experienced symptomatic heart failure, 47% of pertuzumab-treated patients had recovered (defined as 2 consecutive LVEF measurements above 50%) at the data cutoff. The majority of the events (86%) were reported in anthracycline-treated patients. Asymptomatic or mildly symptomatic (NYHA Class II) declines in LVEF ≥ 10% and a drop to < 50% were reported in 3% of pertuzumab-treated patients, of whom 80% recovered at the data cutoff.
- Pertuzumab has not been studied in patients with a pretreatment LVEF value of < 50%, a prior history of CHF, decreases in LVEF to < 50% during prior trastuzumab therapy, or conditions that could impair left ventricular function such as uncontrolled hypertension, recent myocardial infarction, serious cardiac arrhythmia requiring treatment or a cumulative prior anthracycline exposure to > 360 mg/m^2 of doxorubicin or its equivalent.

Embryo-Fetal Toxicity

- Based on its mechanism of action and findings in animal studies, pertuzumab can cause fetal harm when administered to a pregnant woman. Pertuzumab is a HER2/neu receptor antagonist. Cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death have been reported with use of another HER2/neu receptor antagonist (trastuzumab) during pregnancy. In an animal reproduction study, administration of pertuzumab to pregnant cynomolgus monkeys during the period of organogenesis resulted in oligohydramnios, delayed fetal kidney development, and embryo-

fetal death at exposures 2.5 to 20 times the exposure in humans at the recommended dose, based on Cmax.

Infusion-Related Reactions

- Pertuzumab can cause serious infusion reactions, including fatal events.
- In CLEOPATRA, on the first day, when only pertuzumab was administered, infusion-related reactions occurred in 13% of patients and < 1% were Grade 3 or 4. The most common infusion reactions (≥ 1%) were pyrexia, chills, fatigue, headache, asthenia, hypersensitivity, and vomiting. During the second cycle when all drugs were administered on the same day, the most common infusion reactions in the pertuzumab-treated group (≥ 1%) were fatigue, dysgeusia, hypersensitivity, myalgia, and vomiting. In APHINITY, when pertuzumab was administered in combination with trastuzumab and chemotherapy on the same day, infusion-related reactions occurred in 21% of patients with <1% of patients experiencing Grade 3-4 events.
- Observe patients closely for 60 minutes after the first infusion and for 30 minutes after subsequent infusions of pertuzumab. If a significant infusion-related reaction occurs, slow or interrupt the infusion, and administer appropriate medical therapies. Monitor patients carefully until complete resolution of signs and symptoms. Consider permanent discontinuation in patients with severe infusion reactions.

Hypersensitivity Reactions/Anaphylaxis

- Pertuzumab can cause hypersensitivity reactions, including anaphylaxis.
- In CLEOPATRA, the overall frequency of hypersensitivity/anaphylaxis reactions was 11% in pertuzumab-treated patients, with Grade 3 – 4 hypersensitivity reactions and anaphylaxis occurring in 2% of patients.
- In NeoSphere, TRYPHAENA, BERENICE, and APHINITY, hypersensitivity/anaphylaxis events were consistent with those observed in CLEOPATRA. In APHINITY, the overall frequency of hypersensitivity/anaphylaxis was 5% in the pertuzumab treated group. The incidence was highest in the pertuzumab plus TCH treated group (8%) with 1% Grade 3 – 4 events.
- Observe patients closely for hypersensitivity reactions. Severe hypersensitivity, including anaphylaxis and fatal events, have been observed in patients treated with pertuzumab. Angioedema has been described in postmarketing reports. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use prior to administration of pertuzumab. PEBRILZO is contraindicated in patients with known hypersensitivity to pertuzumab or to any of its excipients.

MOST COMMON ADVERSE REACTIONS

Metastatic Breast Cancer

- The most common adverse reactions (> 30%) with PEBRILZO in combination with trastuzumab and docetaxel were diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy.

Neoadjuvant Treatment of Breast Cancer

- The most common adverse reactions (> 30%) with PEBRILZO in combination with trastuzumab and docetaxel were alopecia, diarrhea, nausea, and neutropenia.
- The most common adverse reactions (>30%) with PEBRILZO in combination with trastuzumab and docetaxel when given for 3 cycles following 3 cycles of FEC were fatigue, alopecia, diarrhea, nausea, vomiting, and neutropenia.
- The most common adverse reactions (>30%) with PEBRILZO in combination with docetaxel, carboplatin, and trastuzumab (TCH) were fatigue, alopecia, diarrhea, nausea, vomiting, neutropenia, thrombocytopenia, and anemia.

- The most common adverse reactions (>30%) with PEBRILZO in combination with trastuzumab and paclitaxel when given for 4 cycles following 4 cycles of ddAC were nausea, diarrhea, alopecia, fatigue, constipation, peripheral neuropathy, and headache.
- The most common adverse reactions (>30%) with PEBRILZO in combination with trastuzumab and docetaxel when given for 4 cycles following 4 cycles of FEC were diarrhea, nausea, alopecia, asthenia, constipation, fatigue, mucosal inflammation, vomiting, myalgia, and anemia.

Adjuvant Treatment of Breast Cancer

- The most common adverse reactions (>30%) with PEBRILZO in combination with trastuzumab and chemotherapy were diarrhea, nausea, alopecia, fatigue, peripheral neuropathy and vomiting.

Please refer to the full Patient Information for additional Important Safety Information, including BOXED WARNINGS. 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 LinkedIn: Biocon

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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.