17 September 2026
EMA/CHMP/195428/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pebrilzo

pertuzumab

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pebrilzo, intended for the treatment of breast cancer.

The applicant for this medicinal product is Biocon Biologics Ireland Limited.

Pebrilzo will be available as 420 mg concentrate for solution for infusion. The active substance of Pebrilzo is pertuzumab, a monoclonal antibody (ATC code: L01FD02) 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.

Pebrilzo is a biosimilar medicinal product. It is highly similar to the reference product Perjeta (pertuzumab), which was authorised in the EU on 4 March 2013. Data show that Pebrilzo has comparable quality, safety and efficacy to Perjeta (pertuzumab). More information on biosimilar medicines can be found here.

The full indication is:

Early breast cancer

Pebrilzo 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 (see section 5.1)
- the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence (see section 5.1)

Metastatic breast cancer

Pebrilzo 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

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

Treatment with Pebrilzo should only be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. Pebrilzo should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation facilities are immediately available.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.