12 November 2020
EMA/CHMP/540000/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Phesgo

pertuzumab / trastuzumab

On 12 November 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Phesgo, intended for the treatment of early and metastatic breast cancer.

The applicant for this medicinal product is Roche Registration GmbH.

Phesgo will be available as a solution for injection (600 mg / 600 mg and 1200 mg / 600 mg). The active substances of Phesgo are pertuzumab and trastuzumab, two monoclonal antibodies (ATC code: L01XY02) targeting the human epidermal growth factor receptor 2 (HER2), disrupting HER2 signalling, and also mediating antibody-dependent cell-mediated cytotoxicity.

The benefit of Phesgo is that it is administered as a subcutaneous, fixed-dose combination of pertuzumab and trastuzumab, offering patients a less invasive and faster administration as a single product, compared to the current administration of the approved intravenous pertuzumab and subcutaneous trastuzumab formulations. The most common side effects are alopecia, diarrhoea, nausea, anaemia, asthenia, and arthralgia.

The full indication is:

Early breast cancer (EBC)

Phesgo is indicated for use in combination with 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 (MBC)

Phesgo is indicated for use in combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-

[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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HER2 therapy or chemotherapy for their metastatic disease.

Phesgo should be prescribed by physicians experienced in the administration of anti-cancer agents.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.