



26 April 2018
EMA/258941/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Perjeta pertuzumab

On 26 April 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Perjeta. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to the existing indication as follows²:

“Early breast cancer

Perjeta 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)**

Neoadjuvant treatment of breast cancer

~~Perjeta is indicated for use in combination with trastuzumab and chemotherapy for 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)”~~

Metastatic breast cancer

Perjeta 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.”

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

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

² **New text in bold, removed text as strikethrough**

