



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2012
EMA/CHMP/803313/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Perjeta pertuzumab

On 13 December 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Perjeta, 420 mg, concentrate for solution for infusion intended 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. The applicant for this medicinal product is Roche Registration Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Perjeta is pertuzumab, a recombinant humanised monoclonal antibody (ATC Code L01 XC13) that targets the extracellular dimerization domain (subdomain II) of the human epidermal growth factor receptor 2 protein (HER2), and thereby, blocks ligand-dependent heterodimerisation of HER2 with other HER family members, including EGFR, HER3 and HER4. Perjeta inhibits ligand-initiated intracellular signalling through two major signal pathways, mitogen-activated protein (MAP) kinase and phosphoinositide 3-kinase (PI3K). Inhibition of these signalling pathways can result in cell growth arrest and apoptosis, respectively. In addition, Perjeta mediates antibody-dependent cell-mediated cytotoxicity (ADCC).

The benefits with Perjeta are its ability to improve progression-free survival (PFS), overall survival (OS) and objective response rate (ORR) in patients treated with pertuzumab compared to placebo. The most common side effects were diarrhoea, alopecia, leucopenia and (febrile) neutropenia.

A pharmacovigilance plan for Perjeta will be implemented as part of the marketing authorisation.

The approved indication is: "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." It is proposed that Perjeta be prescribed by physicians experienced in the administration of anticancer agents.

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.



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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Perjeta and therefore recommends the granting of the marketing.