10 December 2020
EMA/CHMP/631955/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enhertu

trastuzumab deruxtecan

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Enhertu, intended for the treatment of metastatic HER2-positive breast cancer. Enhertu was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Daiichi Sankyo Europe GmbH.

Enhertu will be available as 100 mg powder for concentrate for solution for infusion. The active substance of Enhertu is trastuzumab deruxtecan, a monoclonal antibody-drug conjugate (ATC code: L01XC41) that binds to the human epidermal growth factor receptor 2 (HER2), disrupting HER2 signalling and also mediating antibody-dependent cell-mediated cytotoxicity. In addition, after binding, trastuzumab deruxtecan undergoes internalisation and intracellular cleavage, resulting in release of deruxtecan. Upon release, deruxtecan causes DNA damage and apoptotic cell death.

The benefits with Enhertu are improved objective response rate and duration of response in patients who had received two or more prior anti-HER2 based regimens. The most common side effects are nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anaemia, neutropenia, diarrhoea, thrombocytopenia, cough, leucopoenia and headache.

The full indication is:

> Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti HER2 based regimens.

Enhertu should be prescribed by physicians experienced in the use of anticancer medicinal products.

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

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.