18 October 2018
EMA/CHMP/688548/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ogivri

trastuzumab

On 18 October 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ogivri, intended for the treatment of breast and gastric cancer. The applicant for this medicinal product is MYLAN S.A.S.

Ogivri will be available as a 150-mg powder for concentrate for solution for infusion. The active substance of Ogivri is trastuzumab, a monoclonal antibody (ATC code: L01XC03) that binds with high affinity and specificity to HER2 leading to the inhibition of proliferation of tumour cells that overexpress HER2.

Ogivri is a biosimilar medicinal product. It is highly similar to the reference product Herceptin (trastuzumab), which was authorised in the EU on 28 August 2000. Data show that Ogivri has comparable quality, safety and efficacy to Herceptin. More information on biosimilar medicines can be found here.

The full indication is:

> "Breast cancer
>
> *Metastatic breast cancer*
>
> Ogivri is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC):
>
> - as monotherapy for the treatment of those patients who have received at least two chemotherapy regimens for their metastatic disease. Prior chemotherapy must have included at least an anthracycline and a taxane unless patients are unsuitable for these treatments. Hormone receptor positive patients must also have failed hormonal therapy, unless patients are unsuitable for these treatments
> - in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease and for whom an anthracycline is not suitable
> - in combination with docetaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease

[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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- in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab.

Early breast cancer

Ogivri is indicated for the treatment of adult patients with HER2 positive early breast cancer (EBC):

- following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable) (see section 5.1)
- following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel
- in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.
- in combination with neoadjuvant chemotherapy followed by adjuvant Ogivri therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter (see sections 4.4 and 5.1).

Ogivri should only be used in patients with metastatic or EBC whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay (see sections 4.4 and 5.1).

Metastatic gastric cancer

Ogivri in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of adult patients with HER2 positive metastatic adenocarcinoma of the stomach or gastroesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.

Ogivri should only be used in patients with metastatic gastric cancer (MGC) whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory SISH or FISH result, or by an IHC 3+ result. Accurate and validated assay methods should be used (see sections 4.4 and 5.1)."

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.