25 February 2021
EMA/CHMP/53909/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jemperli

dostarlimab

On 25 February 2021, 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 Jemperli, intended for the treatment of certain types of recurrent or advanced endometrial cancer. The applicant for this medicinal product is GlaxoSmithKline (Ireland) Limited.

Jemperli will be available as a solution for infusion (500 mg dostarlimab per 10 ml). The active substance of Jemperli is dostarlimab, an antineoplastic monoclonal antibody (ATC code: L01XC40) which potentiates T-cell responses, including anti-tumour responses through blockade of PD-1 binding to PD L1 and PD L2 ligands.

The benefits with Jemperli are its effects on objective response rate and response duration in patients with mismatch repair deficient (dMMR) or with high microsatellite instability (MSI-H) recurrent or advanced endometrial cancer who have been previously treated. The most common side effects are anaemia, nausea, diarrhoea, vomiting, pruritus, rash, myalgia, pyrexia and hypothyroidism.

The full indication is:

> Jemperli is indicated as monotherapy for the treatment of adult patients with recurrent or advanced mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

Jemperli must be initiated and supervised by specialist physicians experienced in the treatment of cancer.

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

[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 expected to provide comprehensive clinical data at a later stage.

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