



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 July 2017  
EMA/CHMP/426201/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Bavencio avelumab

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bavencio, intended for the treatment of metastatic Merkel cell carcinoma. Bavencio was designated as an orphan medicinal product on 14 December 2015. The applicant for this medicinal product is Merck Serono Europe Limited.

Bavencio will be available as a 20 mg/ml concentrate for solution for infusion. The active substance of Bavencio is avelumab, an antineoplastic agent (ATC code: not yet assigned) that is directed against programmed death ligand 1 (PD-L1). Avelumab binds to PD-L1 and blocks the interaction between PD-L1 and the programmed death 1 (PD-1) and B7.1 receptors.

The benefits with Bavencio are its ability to show tumour responses in patients whether they have or not been treated with chemotherapy. In many patients, the response is of prolonged duration.

The most common side effects are fatigue, nausea, diarrhoea, decreased appetite, constipation, infusion related reaction, weight decreased and vomiting. Serious adverse reactions are immune-related adverse reactions and infusion-related reactions.

The full indication is: "Bavencio is indicated as monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (MCC)." Treatment should be initiated and supervised by a physician 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 granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

