22 February 2024
EMA/CHMP/60465/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

ZYNYZ

retifanlimab

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zynyz[2], intended for the treatment of Merkel cell carcinoma. The applicant for this medicinal product is Incyte Biosciences Distribution B.V.

Zynyz will be available as 500 mg concentrate for solution for infusion. The active substance of Zynyz is retifanlimab, an antineoplastic agent (ATC code: L01FF10) that binds to PD-1 (programmed cell death protein 1) receptor, blocks its interaction with its ligands PD-L1 and PD-L2, and potentiates T-cell response in the tumour microenvironment.

The benefits of Zynyz are its objective response rate and response duration in patients with metastatic or recurrent locally advanced Merkel cell carcinoma not amenable to surgery or radiation.

The full indication is:

> ZYNYZ is indicated as monotherapy for the first-line treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) not amenable to curative surgery or radiation therapy.

Treatment with Zynyz 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.

[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] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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