29 January 2026
EMADOC-1700519818-2841651
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zynyz

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On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Zynyz. The marketing authorisation holder for this medicinal product is Incyte Biosciences Distribution B.V.

The CHMP adopted a new indication as follows:[2]

Squamous cell carcinoma of the anal canal (SCAC)

ZYNYZ is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).

Merkel cell carcinoma (MCC)

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.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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