26 March 2026
EMADOC-1700519818-3000971
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Hetronifly

serplulimab

On 26 March 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 Hetronifly. The marketing authorisation holder for this medicinal product is Accord Healthcare S.L.U.

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

Small cell lung cancer (SCLC)

HETRONIFLY in combination with carboplatin and etoposide is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Oesophageal squamous cell carcinoma (OSCC)

HETRONIFLY in combination with fluoropyrimidine- and platinum-based chemotherapy is indicated for the first-line treatment of adult patients with unresectable, locally advanced, recurrent or metastatic oesophageal squamous cell carcinoma whose tumours express PD-L1 with a CPS ≥ 5.

For information, the CHMP also adopted another new indication on 26 March 2026 for Hetronifly to extend its use to non-small cell lung carcinoma (NSCLC). Information on this change is provided in a dedicated summary of opinion available from the EMA website.

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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