



26 March 2026  
EMADOC-1700519818-2975996  
Committee for Medicinal Products for Human Use (CHMP)

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

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# Hetronify

## 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 Hetronify. The marketing authorisation holder for this medicinal product is Accord Healthcare S.L.U.

The CHMP adopted a new indication as follows:<sup>2</sup>

### **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).

### **Non-small cell lung carcinoma (NSCLC)**

**HETRONIFLY in combination with carboplatin and pemetrexed is indicated for the first-line treatment of adult non-squamous NSCLC patients with no EGFR, ALK or ROS1 positive mutations and who have:**

- **locally advanced NSCLC who are not candidates for surgery or radiotherapy, or**
- **metastatic NSCLC.**

For information, the CHMP adopted another new indication on 26 March 2026 for Hetronify to extend its use to oesophageal squamous cell carcinoma (OSCC). 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.

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

<sup>2</sup> New text in bold

