21 May 2026
EMADOC-1700519818-3134638
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Hetronifly

serplulimab

On 21 May 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:

> HETRONIFLY in combination with carboplatin and nab-paclitaxel is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma.

For information, the full indications for HETRONIFLY will be 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).
>
> 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.
>
> **HETRONIFLY in combination with carboplatin and nab-paclitaxel is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic squamous non-small cell lung carcinoma.**

[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 indication in bold

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.

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.