19 September 2024
EMA/CHMP/424207/2024
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Hetronifly

serplulimab

On 19 September 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 Hetronifly[2], intended for the treatment of extensive-stage small cell lung cancer (ES-SCLC).

The applicant for this medicinal product is Henlius Europe GmbH.

Hetronifly will be available as 10 mg/ml concentrate for solution for infusion. The active substance of Hetronifly is serplulimab, an antineoplastic monoclonal antibody (ATC code: L01FF12). By blocking the binding of PD-1 to PD-L1 and PD-L2, serplulimab potentiates T-cell responses, including anti-tumour responses.

The benefits of Hetronifly in combination with carboplatin and etoposide have been shown in a study involving adults with ES-SCLC who had not been treated with systemic therapy. Hetronifly led to improved overall survival and progression free survival when compared to patients who were treated with carboplatin and etoposide alone.

The most common side effects with Hetronifly combined with carboplatin and etoposide are neutropenia, leukopenia, anaemia, thrombocytopenia, alopecia, nausea, hyperlipidaemia, decreased appetite, hypoproteinaemia, hyponatraemia, hypothyroidism and hyperthyroidism.

The full indication is:

> 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).

Hetronifly should be prescribed and supervised by doctors 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

[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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