30 May 2024
EMA/CHMP/224098/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cejemly

sugemalimab

On 30 May 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 Cejemly, intended for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) in combination with chemotherapy.

The applicant for this medicinal product is SFL Pharmaceuticals Deutschland GmbH.

Cejemly will be available as 600 mg concentrate for solution for infusion. The active substance of Cejemly is sugemalimab, an antineoplastic monoclonal antibody (L01FF11) that potentiates T-cell responses, including anti-tumour responses, through blockade of PD-1 binding to PD-L1 ligands.

In patients with metastatic NSCLC, the benefits of Cejemly in combination with chemotherapy are a clinically meaningful improvement in progression-free survival and overall survival compared with placebo combined with chemotherapy. The most common side effects of Cejemly are anaemia (77.5%), aspartate aminotransferase increase (34.0%), alanine aminotransferase increase (32.0%).

The full indication is:

> Cejemly in combination with platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations.

Cejemly should be prescribed by physicians 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 granted by the European Commission.

[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

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