



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 October 2025
EMADOC-1700519818-2464690
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Cejemly sugemalimab

On 16 October 2025, 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 Cejemly. The marketing authorisation holder for this medicinal product is CStone Pharmaceuticals Ireland Limited.

The CHMP adopted a new indication:

Cejemly as monotherapy is indicated for the treatment of unresectable stage III NSCLC with no sensitising EGFR mutations, or ALK, ROS1 genomic tumour aberrations in adults whose tumours express PD-L1 on $\geq 1\%$ of tumour cells and whose disease has not progressed following platinum-based chemoradiotherapy.

For information, the full indications for Cejemly will now be as follows:²

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 as monotherapy is indicated for the treatment of unresectable stage III NSCLC with no sensitising EGFR mutations, or ALK, ROS1 genomic tumour aberrations in adults whose tumours express PD-L1 on $\geq 1\%$ of tumour cells and whose disease has not progressed following platinum-based chemoradiotherapy.

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 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 New text in bold

