



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2023
EMA/CHMP/285608/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Imjudo

tremelimumab

On 22 June 2023, 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 IMJUDO. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new indication for the treatment of metastatic non-small cell lung cancer. For information, the full indications for Imjudo will therefore be as follows²:

IMJUDO in combination with durvalumab is indicated for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma (HCC).

IMJUDO in combination with durvalumab and 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 positive mutations.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available 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**

