15 December 2022
EMA/904398/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Imjudo

tremelimumab

On 15 December 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imjudo, intended for the treatment of hepatocellular carcinoma. The applicant for this medicinal product is AstraZeneca AB.

Imjudo will be available as a 20 mg/ml concentrate for solution for infusion. The active substance of Imjudo is tremelimumab, a monoclonal antibody (ATC code: L01FX20). It binds to CTLA-4, which is primarily expressed on the surface of activated T lymphocytes, and thus enhances T-cell activation and proliferation, resulting in increased T-cell diversity and enhanced anti-tumour activity.

The benefit of Imjudo in combination with durvalumab is a significant improvement in overall survival compared with the standard of care, sorafenib, as observed in a randomised, open-label, multicentre Phase III study in patients with unresectable hepatocellular carcinoma. The most common side effects are rash, pruritus, diarrhoea, abdominal pain, AST increased, pyrexia, hypothyroidism, cough/productive cough, oedema peripheral and lipase increased.

The full indication is:

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

Imjudo 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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