EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2022
EMA/CHMP/925958/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tremelimumab AstraZeneca

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 Tremelimumab AstraZeneca, intended for the treatment of metastatic non-small cell lung cancer (NSCLC). The applicant for this medicinal product is AstraZeneca AB.

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

The benefits of Tremelimumab AstraZeneca in combination with durvalumab and platinum-based chemotherapy, in the first-line treatment of metastatic NSCLC, are improvements in overall survival and progression-free survival compared with standard of care (chemotherapy), as observed in a randomised, open-label Phase III study. The most common side effects are anaemia, nausea, neutropenia, fatigue, rash, thrombocytopenia and diarrhoea.

The full indication is:

> Tremelimumab AstraZeneca 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.

Tremelimumab AstraZeneca 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union