26 July 2018
EMA/CHMP/458931/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Imfinzi

durvalumab

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Imfinzi, intended for the treatment of non-small cell lung cancer (NSCLC). The applicant for this medicinal product is AstraZeneca AB.

Imfinzi will be available as a 50-mg/ml concentrate for solution for infusion. The active substance of Imfinzi is durvalumab, an antineoplastic monoclonal antibody (ATC code: L01XC28) that potentiates T-cell response, including anti-tumour response, through blockade of PD-L1 binding to PD-1.

The benefits with Imfinzi are its ability to improve survival and progression-free survival compared with placebo in patients whose disease has not progressed following chemoradiation therapy.

The most common side effects are cough, upper respiratory tract infections, rash and diarrhoea. Imfinzi is also associated with immune-related adverse reactions including pneumonitis, hepatitis, colitis, hypothyroidism or hyperthyroidism, adrenal insufficiency, type 1 diabetes mellitus, hypophysitis or hypopituitarism, nephritis and rash.

The full indication is:

"Imfinzi as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy."

It is proposed that Imfinzi 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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