21 July 2022
EMA/CHMP/617724/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Opdualag

nivolumab / relatlimab

On 21 July 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 Opdualag, intended for the treatment of melanoma. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Opdualag will be available as a 240 mg / 80 mg concentrate for solution for infusion. The active substances of Opdualag are nivolumab and relatlimab, two monoclonal antibodies (ATC code: L01XY03). Nivolumab is a programmed death-1 inhibitor (anti-PD-1) and relatlimab is a lymphocyte-activation gene-3 inhibitor (anti-LAG-3). Their combined use increases T cell activation and cytokine secretion to inhibit tumour growth and promote tumour regression.

The benefit of Opdualag is a 3.7-month gain in progression-free survival over nivolumab monotherapy in the PD-L1 < 1% group, as observed in a randomised, double-blind, multicentre pivotal study in patients with previously untreated metastatic or unresectable melanoma. The most common side effects are fatigue, musculoskeletal pain, rash, arthralgia, diarrhoea, pruritus, headache, nausea, cough, decreased appetite, hypothyroidism, abdominal pain, vitiligo, pyrexia, constipation, urinary tract infection, dyspnoea and vomiting.

The full indication is:

> Opdualag is indicated for the first line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older with tumour cell PD-L1 expression < 1%.

Treatment with Opdualag must be initiated and supervised 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

[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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