23 April 2015
EMA/CHMP/76686/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Opdivo

nivolumab

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Opdivo, intended for the treatment of advanced (unresectable or metastatic) melanoma in adults. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Opdivo will be available as a 10 mg/ml concentrate for solution for infusion. The active substance of Opdivo is nivolumab, an antineoplastic monoclonal antibody (ATC code L01XC17). Opdivo potentiates T cell responses, including anti-tumour responses, through blockade of PD 1 binding to PD L1 and PD L2 ligands.

The benefits obtained with Opdivo are an increase in overall survival over dacarbazine (HR = 0.42; 99.79%CI: 0.25, 0.73; p-value < 0.0001) in patients with advanced (unresectable or metastatic) melanoma in adults who have not received prior therapy and an improvement in overall response rate for nivolumab compared to investigator's choice of treatment (31.7% versus 10.6%, respectively) in adults who had received previous therapy.

The most common side effects are fatigue, pruritus, nausea, diarrhoea, and rash. Nivolumab is associated with immune-related adverse reactions including endocrine abnormalities, diarrhoea/colitis, hepatitis, pneumonitis, nephritis and rash.

The full indication is: "Opdivo as monotherapy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults". It is proposed that Opdivo 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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