21 May 2015
EMA/CHMP/298313/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Keytruda

pembrolizumab

On 21 May 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 Keytruda, intended as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Keytruda will be available as a 50 mg powder for concentrate for solution for infusion. The active substance of Keytruda is pembrolizumab, an antineoplastic monoclonal antibody (ATC code L01XC18) that potentiates T cell responses, including anti-tumour responses, through blockade of PD-1 binding to PD-L1 and PD-L2 ligands.

The benefit of Keytruda has been reported in adult patients with advanced (unresectable or metastatic) melanoma who were either ipilimumab naive (OS HR=0.69, 95%CI: 0.52, 0.90; p-value<0.00358; PFS HR=0.58; 95%CI: 0.47, 0.72; p-value<0.00001 in comparison to ipilimumab) or previously treated with ipilimumab (PFS HR=0.57; 95%CI: 0.45, 0.73; p-value<0.0001 in comparison to chemotherapy).

The most common side effects are diarrhoea, nausea, pruritus, rash, arthralgia and fatigue. Keytruda is associated with immune-related adverse reactions including pneumonitis, colitis, hepatitis, nephritis, endocrinopathies, uveitis, myositis, pancreatitis, and severe skin reactions.

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