21 May 2015
EMA/CHMP/310230/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nivolumab BMS

nivolumab

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 Nivolumab BMS, intended for the treatment of adults with locally advanced or metastatic squamous non-small cell lung cancer (NSCLC). The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

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

The benefits with Nivolumab BMS are an increase in overall survival over docetaxel (HR = 0.59; 96.85% CI: 0.43, 0.81; p-value = 0.0002) and an improvement in objective response rate compared with docetaxel (20% versus 8.8%, respectively) in patients with locally advanced or metastatic squamous NSCLC who received prior chemotherapy.

The most common side effects are fatigue, decreased appetite, 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: "Nivolumab BMS is indicated for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults". It is proposed that Nivolumab BMS 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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