1 April 2016
EMA/CHMP/231518/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Opdivo

nivolumab

On 1 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Opdivo. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted an extension to the indication for melanoma as follows:

> "Opdivo as monotherapy **or in combination with ipilimumab** is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults.
>
> **Relative to nivolumab monotherapy, an increase in progression-free survival (PFS) for the combination of nivolumab with ipilimumab is established only in patients with low tumour PD-L1 expression (see section 4.4 and 5.1)."**

For information, the full indications for Opdivo will be as follows:

> "Melanoma
>
> Opdivo as monotherapy or in combination with ipilimumab is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults.
>
> Relative to nivolumab monotherapy, an increase in progression-free survival (PFS) for the combination of nivolumab with ipilimumab is established only in patients with low tumour PD-L1 expression (see section 4.4 and 5.1).
>
> Non-Small Cell Lung Cancer (NSCLC)
>
> Opdivo is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy in adults.
>
> Renal Cell Carcinoma (RCC)
>
> Opdivo as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults."

[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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Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.