20 May 2021
EMA/CHMP/264429/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Opdivo

nivolumab

On 20 May 2021, 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 a new indication as follows:

> Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) colorectal cancer (CRC)
>
> Opdivo in combination with ipilimumab is indicated for the treatment of adult patients with mismatch repair deficient or microsatellite instability high metastatic colorectal cancer after prior fluoropyrimidine based combination chemotherapy (see section 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) and overall survival (OS) for the combination of nivolumab with ipilimumab is established only in patients with low tumour PD L1 expression (see sections 4.4 and 5.1).
>
> Adjuvant treatment of melanoma
>
> Opdivo as monotherapy is indicated for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection (see section 5.1).

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Non small cell lung cancer (NSCLC)

Opdivo in combination with ipilimumab and 2 cycles of platinum-based chemotherapy is indicated for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours have no sensitising EGFR mutation or ALK translocation.

Opdivo as monotherapy is indicated for the treatment of locally advanced or metastatic non small cell lung cancer after prior chemotherapy in adults.

Malignant pleural mesothelioma (MPM)

Opdivo in combination with ipilimumab is indicated for the first line treatment of adult patients with unresectable malignant pleural mesothelioma.

Renal cell carcinoma (RCC)

Opdivo as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults.

Opdivo in combination with ipilimumab is indicated for the first line treatment of adult patients with intermediate/poor risk advanced renal cell carcinoma (see section 5.1).

Opdivo in combination with cabozantinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (see section 5.1).

Classical Hodgkin lymphoma (cHL)

Opdivo as monotherapy is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.

Squamous cell cancer of the head and neck (SCCHN)

Opdivo as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell cancer of the head and neck in adults progressing on or after platinum based therapy (see section 5.1).

Urothelial carcinoma

Opdivo as monotherapy is indicated for the treatment of locally advanced unresectable or metastatic urothelial carcinoma in adults after failure of prior platinum containing therapy.

Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) colorectal cancer (CRC)

Opdivo in combination with ipilimumab is indicated for the treatment of adult patients with mismatch repair deficient or microsatellite instability high metastatic colorectal cancer after prior fluoropyrimidine based combination chemotherapy (see section 5.1).

Oesophageal squamous cell carcinoma (OSCC)

Opdivo as monotherapy is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.

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.