27 March 2025
EMA/CHMP/108241/2025
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Opdivo

nivolumab

On 27 March 2025, 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 pharmaceutical form, solution for injection, a new strength, 600 mg, and a new route of administration, subcutaneous use.

For information, the full indications for Opdivo solution for injection 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 (see section 4.2).
>
> 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 Stage IIB or IIC melanoma, or melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection (see section 5.1).
>
> Non small cell lung cancer (NSCLC)
>
> OPDIVO as monotherapy is indicated for the treatment of locally advanced or metastatic non small cell lung cancer after prior chemotherapy in adults.
>
> Renal cell carcinoma (RCC)
>
> OPDIVO as monotherapy is indicated for the treatment of advanced renal cell carcinoma after

[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
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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 sections 4.2 and 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).

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 in combination with cisplatin and gemcitabine is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma (see sections 4.2 and 5.1).

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.

Adjuvant treatment of urothelial carcinoma

OPDIVO as monotherapy is indicated for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD L1 expression ≥ 1%, who are at high risk of recurrence after undergoing radical resection of MIUC (see section 5.1).

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 colorectal cancer in the following settings:

first-line treatment of unresectable or metastatic colorectal cancer (see sections 4.2 and 5.1);

treatment of metastatic colorectal cancer after prior fluoropyrimidine based combination chemotherapy (see sections 4.2 and 5.1).

Oesophageal squamous cell carcinoma (OSCC)

OPDIVO in combination with fluoropyrimidine and platinum-based combination chemotherapy is indicated for the first line treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma with tumour cell PD L1 expression ≥ 1%.

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.

Adjuvant treatment of oesophageal or gastro oesophageal junction cancer (OC or GEJC)

OPDIVO as monotherapy is indicated for the adjuvant treatment of adult patients with oesophageal or gastro oesophageal junction cancer who have residual pathologic disease following prior neoadjuvant chemoradiotherapy (see section 5.1).

Gastric, gastro oesophageal junction (GEJ) or oesophageal adenocarcinoma

OPDIVO in combination with fluoropyrimidine and platinum-based combination chemotherapy is indicated for the first line treatment of adult patients with HER2 negative advanced or metastatic

gastric, gastro oesophageal junction or oesophageal adenocarcinoma whose tumours express PD L1 with a combined positive score (CPS) ≥ 5.

For information, the full indications for Opdivo will be available in the updated summary of product characteristics (SmPC).

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