



26 April 2023  
EMA/CHMP/167320/2023  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Yervoy ipilimumab

On 26 April 2023, 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 Yervoy. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

#### Melanoma

YERVOY as monotherapy or **in combination with nivolumab** is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older (see section 4.4).

~~YERVOY in combination with nivolumab 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).

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

#### Melanoma

YERVOY as monotherapy or in combination with nivolumab is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older (see section 4.4).

Relative to nivolumab monotherapy, an increase in progression-free survival (PFS) and overall

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough



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).

#### Renal cell carcinoma (RCC)

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

#### Non-small cell lung cancer (NSCLC)

YERVOY in combination with nivolumab 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.

#### Malignant pleural mesothelioma (MPM)

YERVOY in combination with nivolumab is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

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

YERVOY in combination with nivolumab 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)

YERVOY in combination with nivolumab 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  $\geq 1\%$ .

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.