



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
EMA/CHMP/98542/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tevimbra tislelizumab

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 Tevimbra. The marketing authorisation holder for this medicinal product is BeiGene Ireland Limited.

The CHMP adopted a new indication as follows:

Small Cell Lung Cancer (SCLC)

Tevimbra, in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage SCLC.

For information, the full indications for Tevimbra will now be:²

Non-small cell lung cancer (NSCLC)

Tevimbra, in combination with pemetrexed and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on $\geq 50\%$ of tumour cells with no EGFR or ALK positive mutations and who have:

- locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or
- metastatic NSCLC.

Tevimbra, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of adult patients with squamous NSCLC who have:

- locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation,
- or metastatic NSCLC.

Tevimbra as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior platinum-based therapy. Patients with EGFR mutant or ALK

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

² New text in bold



positive NSCLC should also have received targeted therapies before receiving tislelizumab.

Small Cell Lung Cancer (SCLC)

Tevimbra, in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage SCLC.

Gastric or gastroesophageal junction (G/GEJ) adenocarcinoma

Tevimbra, in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adult patients with HER-2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score $\geq 5\%$ (see section 5.1).

Oesophageal squamous cell carcinoma (OSCC)

Tevimbra, in combination with platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic OSCC whose tumours express PD-L1 with a TAP score $\geq 5\%$ (see section 5.1).

Tevimbra as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic OSCC after prior platinum-based chemotherapy.

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.