22 February 2024
EMA/CHMP/59203/2024
Committee for Medicinal Products for Human Use (CHMP)

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

# Tizveni

tislelizumab

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tizveni, intended for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) either in monotherapy or in combination with chemotherapy. The applicant for this medicinal product is Beigene Ireland Limited.

Tizveni will be available as a 100 mg concentrate for solution for infusion. The active substance of Tizveni is tislelizumab, an antineoplastic agent (ATC code: L01FF09). Tislelizumab is a humanised IgG4 variant monoclonal antibody that potentiates T-cell responses, including anti-tumour responses, through blockade of PD-1 binding to PD-L1 and PD-L2 ligands.

The benefit of Tizveni is an improvement in overall survival and progression free survival in patients with locally advanced or metastatic NSCLC, as shown in three open-label, randomised phase 3 studies comparing Tizveni (either in monotherapy or in combination) with chemotherapy. The most common side effects are anaemia, fatigue and increased AST.

The full indication is:

> Tizveni in combination with pemetrexed and platinum-containing chemotherapy is indicated for the first-line treatment of adult patients with non-squamous non-small cell lung cancer whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have:
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> - locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or
> - metastatic NSCLC
>
> Tizveni in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of adult patients with squamous non-small cell lung cancer who have:

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

Tizveni as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer after prior platinum-based therapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving tislelizumab.

Tizveni should be prescribed by physicians experienced in the treatment of cancer.

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