EMA/87936/2024
EMEA/H/C/005542

Tizveni (*tislelizumab*)

An overview of Tizveni and why it is authorised in the EU

What is Tizveni and what is it used for?

Tizveni is a cancer medicine for non-small cell lung cancer (NSCLC). It is used in adults to treat:

- non-squamous NSCLC, in combination with pemetrexed (a chemotherapy medicine that kills cells that are dividing, such as cancer cells) and cisplatin or carboplatin (other chemotherapy medicines), when the disease is metastatic (meaning it has spread to other parts of the body) or when the tumour is locally advanced (meaning it has spread into tissues around the lungs but not to other parts of the body) and cannot be treated with surgery or platinum-based medicines. It is used when at least 50% of the tumour cells have the protein PD-L1 on their surface and the cancer has no mutations (changes) in the *EGFR* and *ALK* genes;
- squamous NSCLC, in combination with carboplatin and paclitaxel or nab-paclitaxel (other cancer medicines), when the disease is metastatic or when the tumour is locally advanced and cannot be treated with surgery or platinum-based medicines;
- NSCLC that is locally advanced or metastatic, when cancer treatment with platinum-based medicines has not worked well enough. In these patients, Tizveni is used on its own. Patients whose cancer has an *EGFR* or *ALK* mutation should also have received medicines that target these mutations before starting Tizveni.

Tizveni contains the active substance tislelizumab.

How is Tizveni used?

Treatment with Tizveni must be started and supervised by a doctor experienced in treating cancer. The medicine can only be obtained with a prescription.

Tizveni is given as an infusion (drip) into a vein every three weeks, and treatment can continue until the disease gets worse. The doctor may delay doses if certain side effects occur or stop treatment altogether if side effects are severe.

For more information about using Tizveni, see the package leaflet or contact your doctor or pharmacist.

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

How does Tizveni work?

The active substance in Tizveni, tislelizumab, is a monoclonal antibody (a type of protein) that has been designed to block a receptor (target) called PD-1 on the so-called T cells of the immune system (the body's natural defences). Some cancers can make proteins (PD-L1 and PD-L2) that combine with PD-1 to switch off the activity of the T cells, preventing them from attacking the cancer. By blocking PD-1, tislelizumab stops the cancer switching off the T cells, thereby increasing the ability of the immune system to kill the cancer cells.

What benefits of Tizveni have been shown in studies?

The benefits of Tizveni were shown in three main studies.

In one main study involving 334 adults with non-squamous NSCLC, patients were given Tizveni in combination with pemetrexed plus either cisplatin or carboplatin or only pemetrexed and cisplatin or carboplatin: after starting treatment patients treated with Tizveni combination therapy lived, on average, for 9.8 months without their disease getting worse, compared with 7.6 months for patients who were given pemetrexed and cisplatin or carboplatin only. In the sub-group of 110 patients in whom more than 50% of the NSCLC cells had the PD-L1 protein on their surface, those treated with Tizveni combination therapy lived for 14.6 months without their disease getting worse, on average, compared with 4.6 months for those who only received pemetrexed and cisplatin or carboplatin.

In a second main study involving 360 adults with squamous NSCLC, patients received Tizveni in combination with carboplatin and either paclitaxel or nab-paclitaxel, or carboplatin and paclitaxel alone: after starting treatment, patients treated with either Tizveni combination therapy lived, on average, for 7.7 months (Tizveni/carboplatin/paclitaxel) and 9.6 months (Tizveni/carboplatin/nab-paclitaxel) without their disease getting worse, compared with 5.5 months for patients who were given carboplatin and paclitaxel only.

In a third main study involving 805 adults with NSCLC who had previously received platinum-based chemotherapy, patients were given Tizveni or docetaxel (another cancer medicine): patients given Tizveni lived, on average, for 16.9 months after starting treatment, compared with 11.9 months for patients who received docetaxel.

What are the risks associated with Tizveni?

For the full list of side effects and restrictions with Tizveni, see the package leaflet.

Tizveni is associated with side effects related to the activity of the immune system, which can be serious; most of these side effects go away with appropriate treatment or on stopping the medicine.

When used in combination with chemotherapy, the most common side effects with Tizveni (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), thrombocytopenia (low levels of blood platelets), increased levels of liver enzymes, tiredness, nausea (feeling sick), decreased appetite and rash. When used on its own, the most common side effects with Tizveni (which may affect more than 1 in 10 people) include anaemia, tiredness and increased levels of liver enzymes.

Why is Tizveni authorised in the EU?

Tizveni, in combination with other cancer medicines, was shown to be effective at improving progression-free survival (how long patients lived without their disease getting worse) in patients with locally advanced or metastatic NSCLC. In patients whose NSCLC did not sufficiently respond to prior

chemotherapy, treatment with Tizveni had a meaningful effect on how long patients lived. The side effects of Tizveni were comparable to those of similar cancer medicines. The European Medicines Agency therefore decided that Tizveni's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Tizveni?

Treatment with Tizveni can lead to serious side effects related to the activity of the immune system, which are presented in the package leaflet. The company that markets Tizveni will make a patient card available to people using the medicine, which informs them about the risks of these immune-related side effects and gives instructions on when to contact their doctor if they experience symptoms.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tizveni have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tizveni are continuously monitored. Suspected side effects reported with Tizveni are carefully evaluated and any necessary action taken to protect patients.

Other information about Tizveni

Tizveni received a marketing authorisation valid throughout the EU on 19 April 2024.

Further information on Tizveni can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Tizveni.

This overview was last updated in 04-2024.