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Tevimbra (*tislelizumab*)

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

What is Tevimbra and what is it used for?

Non-small cell lung cancer

Tevimbra is used to treat non-small cell lung cancer (NSCLC) that is advanced or has spread to other parts of the body (metastatic).

Tevimbra is used together with chemotherapy as first-line treatment for patients whose cancer cannot be removed surgically (unresectable) or treated with a combination of chemotherapy and radiotherapy. These include patients whose cancers produce certain levels of a protein known as PD-L1.

Tevimbra is also used on its own for patients with NSCLC who have already had chemotherapy.

Gastric or gastroesophageal junction adenocarcinoma

Tevimbra is used to treat adults with gastric or gastro-oesophageal junction adenocarcinoma (a type of cancer of the stomach or the transition between the stomach and oesophagus) that is locally advanced and unresectable or that is metastatic.

It is used as first-line treatment together with chemotherapy containing platinum and fluoropyrimidine in patients whose cancer is HER2-negative (this means that the cancer does not have large quantities of a protein called HER2). In addition, Tevimbra should only be used when the cancer produces certain levels of PD-L1, with a tumour area positivity (TAP) score of at least 5% (the TAP score is based on how much of the tumor is made up of PD-L1-positive tumor cells and immune cells).

Oesophageal cancer

Tevimbra is also used to treat squamous oesophageal cancer (cancer of the oesophagus, the passage from the mouth to the stomach) if the cancer is advanced, metastatic or unresectable. It is used after cancer treatment with platinum-based medicines has not worked well enough.

It is used in combination with platinum-based medicines in patients whose tumours produce certain levels of PD-L1 with a TAP score of at least 5%.

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Oesophageal cancer is rare, and Tevimbra was designated an 'orphan medicine' (a medicine used in rare diseases) on 13 November 2020. Further information on the orphan designation can be found on the EMA website.

Tevimbra contains the active substance tislelizumab.

How is Tevimbra used?

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

Tevimbra 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 Tevimbra, see the package leaflet or contact your doctor or pharmacist.

How does Tevimbra work?

The active substance in Tevimbra, tislelizumab, is a monoclonal antibody, a protein that has been designed to block a receptor (target) called PD-1 on certain 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 immune cells, preventing them from attacking the cancer. By blocking PD-1, tislelizumab stops the cancer switching off these immune cells, thereby increasing the ability of the immune system to kill the cancer cells.

What benefits of Tevimbra have been shown in studies?

Non-small cell lung cancer

In a study of 360 patients with a type of NSCLC known as squamous NSCLC, patients who received Tevimbra in combination with chemotherapy lived longer without their disease getting worse than those given only chemotherapy: around 7.7 months and 9.6 months depending on the combination compared with 5.5 months for chemotherapy alone.

In another study of 334 patients with non-squamous NSCLC whose tumours tested strongly for PD-L1, patients who received Tevimbra with chemotherapy lived for around 14.6 months without their disease getting worse compared with 4.6 months for patients receiving chemotherapy alone. In both combination studies, patients given Tevimbra also lived longer on average.

A third study, involving 805 patients with NSCLC who had previously had chemotherapy, showed that Tevimbra alone was more effective than docetaxel. In this study, patients who received Tevimbra lived on average for around 17 months while patients treated with docetaxel lived on average for around 12 months.

Oesophageal cancer

A main study involved 512 adults with advanced or metastatic squamous oesophageal cancer whose disease had worsened after treatment with platinum-based chemotherapy. Patients treated with Tevimbra lived on average for 8.6 months compared with an average of 6.3 months for patients treated with other cancer medicines (paclitaxel, docetaxel or irinotecan).

Another main study in 649 patients with unresectable, locally advanced, recurrent or metastatic squamous oesophageal cancer compared treatment with Tevimbra in combination with chemotherapy with treatment with placebo plus chemotherapy. Patients treated with Tevimbra and chemotherapy lived on average for 19.1 months compared with 10.0 months for patients treated with placebo and chemotherapy. In addition, patients given Tevimbra and chemotherapy lived for 8.2 months without their disease getting worse, compared with 5.5 months for those given placebo and chemotherapy.

Gastric or gastroesophageal junction adenocarcinoma

A main study involved 997 adults with locally advanced, unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma that was HER2 negative. Patients had not received systemic treatment for their cancer before and were given Tevimbra and chemotherapy or placebo with chemotherapy. Among the 546 patients who had a PD-L1 TAP score of at least 5%, those who were treated with Tevimbra and chemotherapy lived on average for 16.4 months compared with 12.8 months for patients treated with placebo and chemotherapy. In addition, patients on Tevimbra and chemotherapy lived for 7.2 months without their disease getting worse, compared with 5.9 months for those given placebo and chemotherapy.

What are the risks associated with Tevimbra?

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

The most common side effects with Tevimbra when given alone (which may affect more than 1 in 5 people) include anaemia (low levels of red blood cell), tiredness and raised levels of the liver enzyme aspartate aminotransferase (which may indicate liver damage). The most common side effects with Tevimbra when given together with chemotherapy (which may affect more than 1 in 5 people) include neutropenia (low levels of neutrophils, a type of white blood cell), anaemia, thrombocytopenia (low levels of platelets in the blood), nausea (sickness), tiredness, decreased appetite, raised levels of the liver enzymes aspartate aminotransferase and alanine aminotransferase, diarrhoea and rash.

Why is Tevimbra authorised in the EU?

Tevimbra is effective at improving survival and delaying the worsening of NSCLC. It is also effective at improving survival in patients with advanced or metastatic squamous oesophageal cancer and advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma. The side effects of this medicine are considered manageable and comparable to those of similar cancer medicines. The European Medicines Agency therefore decided that Tevimbra’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 Tevimbra?

The company that markets Tevimbra will provide patients with an alert card to inform them about the risks of potential immune-related side effects and give 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 Tevimbra have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Tevimbra

Tevimbra received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 12-2024.