EMA/361473/2024
EMEA/H/C/004143

Tecentriq (*atezolizumab*)

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

What is Tecentriq and what is it used for?

Tecentriq is a medicine used to treat the following cancers:

- urothelial cancer (cancer of the bladder and urinary system);
- non-small cell lung cancer (NSCLC);
- small cell lung cancer (SCLC);
- a type of breast cancer known as triple-negative breast cancer;
- hepatocellular carcinoma, a cancer that starts in the liver.

Tecentriq is used either on its own or in combination with other treatments for cancers that are advanced or have spread to other parts of the body. In some cases, it is used after surgery or after other cancer treatments.

The doctor may need to confirm that the cancer cells produce a certain amount of a protein called PD-L1, and that particular genetic mutations known to reduce the medicine's effectiveness are not present. For more information about the use of Tecentriq, see the package leaflet.

Tecentriq contains the active substance atezolizumab.

How is Tecentriq used?

Tecentriq is given as an infusion (drip) into a vein every 2, 3 or 4 weeks, or as an injection under the skin every 3 weeks. Depending on the type of cancer, patients are treated either for one year or for as long as they benefit from treatment, unless they have unmanageable side effects. The doctor may stop treatment if the patient has certain side effects involving the immune system (the body's defence system), including inflammation of various body organs or endocrine (glandular) disorders. For more information about using Tecentriq, see the package leaflet or contact your doctor or pharmacist.

Tecentriq can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating cancer.

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How does Tecentriq work?

The active substance in Tecentriq, atezolizumab, is a monoclonal antibody (a type of protein) designed to attach to a protein called PD-L1, which is present on many cancer cells.

PD-L1 switches off immune cells that would otherwise attack cancer cells. By attaching to PD-L1, Tecentriq reduces its effects and so increases the immune system's ability to attack cancer cells and thereby slows down progression of the disease.

What benefits of Tecentriq have been shown in studies?

Urothelial cancer

Tecentriq can reduce the size of tumours in patients with urothelial cancer that is advanced or has spread. In a study of 429 patients, the cancer shrank or was eliminated after Tecentriq treatment in 23% of patients who were not eligible for platinum chemotherapy and in 16% of patients who previously had platinum chemotherapy.

In another study involving 931 patients with urothelial cancer, those given Tecentriq lived slightly longer (8.6 months) on average than patients given chemotherapy (8 months) although the difference could be due to chance. Response was seen even in patients whose cancer cells did not produce much PD-L1.

Lung cancer

Non-small cell lung cancer

In patients with non-small cell lung cancer that is advanced or has spread, Tecentriq is more effective than docetaxel (another cancer medicine) at prolonging patients' lives. In one main study of 850 patients, those given Tecentriq lived for 14 months on average while those given docetaxel lived for 10 months. In a second study of 287 patients, patients on Tecentriq lived for 13 months on average compared with 10 months for patients on docetaxel.

In another main study of 1,202 patients with advanced non-small cell lung cancer which has spread and who had not received chemotherapy before, patients given Tecentriq together with paclitaxel, carboplatin and bevacizumab (other cancer medicines) lived on average for 8.4 months without their disease getting worse while those given paclitaxel, carboplatin and bevacizumab lived on average for 6.8 months without their disease getting worse. Overall, patients given Tecentriq with the other medicines lived for 19.8 months on average compared with 14.9 months for patients given the same medicines without Tecentriq.

Another study investigated the effect of Tecentriq in 679 previously untreated patients with NSCLC who did not have a type of cancer known as EGFR mutant or ALK-positive NSCLC. Patients lived on average for 18.6 months when they were given Tecentriq with carboplatin plus nab-paclitaxel compared with 13.9 months when given the combination without Tecentriq. In addition, patients lived for about 7 months without their disease getting worse when they received the Tecentriq combination compared with 5.5 months without Tecentriq.

In a further study in 205 patients with metastatic non-small cell lung cancer who had not received chemotherapy before, patients treated with Tecentriq lived for 20.2 months on average compared with 14.7 months for those who received platinum-based chemotherapy and either pemetrexed or gemcitabine.

Tecentriq was shown to be effective in patients with early-stage NSCLC without EGFR or ALK mutations in which more than 50% of the cancer cells presented PD-L1 on their surface, and who had undergone surgery to completely remove the cancer before receiving platinum-based therapy. After approximately 32 months, around 77% of patients who received Tecentriq (82 out of 106) had no sign of the cancer coming back, compared with 56% (58 out of 103) of patients who received standard cancer treatments. At the time of authorisation, no benefit was observed in patients with cancer cells that presented lower levels of PD-L1 on their surface.

A further study involved 453 patients with advanced, recurrent or metastatic NSCLC who had not previously received systemic (whole body) treatment and who could not receive platinum-based therapy. They received either Tecentriq or chemotherapy (vinorelbine or gemcitabine). Patients who received Tecentriq lived on average for 10.3 months compared with 9.2 months for those who received chemotherapy.

Small cell lung cancer

In a study of 403 patients with the generally more aggressive small cell lung cancer, patients lived for 12.3 months on average when Tecentriq was added to carboplatin plus etoposide, compared with 10.3 months when placebo (a dummy treatment) was added instead. In addition, patients given the Tecentriq combination lived for 5.2 months on average without their disease getting worse compared with 4.3 months for patients who were not given Tecentriq.

Breast cancer

A study of 902 patients with a type of breast cancer known as triple-negative breast cancer looked at the effect of combining Tecentriq with nab-paclitaxel. Patients whose cancer produced the PD-L1 protein up to a certain level lived for an average of 25 months on the Tecentriq plus nab-paclitaxel combination compared with 18 months when given placebo plus nab-paclitaxel. Patients in the Tecentriq group also lived for longer without their disease getting worse (7.5 months versus 5.3).

Hepatocellular carcinoma

A study involved 501 patients with hepatocellular carcinoma that had spread and had not been treated previously. Patients treated with Tecentriq in combination with bevacizumab lived on average for 6.8 months without their disease getting worse, compared to 4.3 months for patients treated with sorafenib.

What are the risks associated with Tecentriq?

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

The side effects of Tecentriq are mostly related to the activity of the immune system, which may cause inflammation of body organs and tissues and can be serious. The most common side effects with Tecentriq when used on its own (which may affect more than 1 in 10 people) include tiredness, reduced appetite, nausea (feeling sick), vomiting, cough, dyspnoea (difficulty breathing), diarrhoea, rash, fever, headache, pain in the back or joints, weakness, itching and urinary tract (structures that carry urine) infection.

The most common side effects with Tecentriq when used with other cancer medicines (which may affect more than 2 in 10 people) include peripheral neuropathy (nerve damage in the hands and feet), nausea, anaemia (low red blood cell counts), neutropenia (low white blood cell counts), alopecia (loss of hair), thrombocytopenia (low platelet counts), rash, tiredness, constipation, reduced appetite and diarrhoea.

In addition, when Tecentriq is given as an injection under the skin, reaction at the site of injection may occur in up to 1 in 10 people.

Why is Tecentriq authorised in the EU?

In urothelial cancer, Tecentriq has been shown to reduce tumour size in patients who have been treated with platinum chemotherapy or who are not eligible for such treatment. Tecentriq can also prolong the time patients with lung cancer, triple-negative breast cancer and hepatocellular carcinoma live.

Tecentriq's side effects when used alone are less troublesome than standard chemotherapy treatments. When Tecentriq is used in combination with other cancer medicines, the side effects are more severe but are considered manageable.

The European Medicines Agency therefore decided that Tecentriq'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 Tecentriq?

The company that markets Tecentriq provides an educational programme for patients and healthcare professionals to explain that serious immune-related side effects can occur during treatment and what they should do to minimise risks.

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

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

Other information about Tecentriq

Tecentriq received a marketing authorisation valid throughout the EU on 21 September 2017.

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

This overview was last updated in 08-2024.