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Withdrawal of application to change the marketing authorisation for Tecentriq (*atezolizumab*)

Roche Registration GmbH withdrew its application for the use of Tecentriq to treat metastatic urothelial cancer in combination with platinum-based therapy in patients who had not been treated before.

The company withdrew the application on 8 January 2021.

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine already used to treat:

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

For urothelial cancer, Tecentriq is used on its own in patients who had already received platinum-based chemotherapy (another type of cancer medicine) or in patients who cannot receive platinum-based therapy and whose cancer cells have a certain amount of a protein called PD-L1.

Tecentriq has been authorised in the EU since September 2017.

Tecentriq contains the active substance atezolizumab and is given as an infusion (drip) into a vein

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

What change had the company applied for?

The company applied to extend the use of Tecentriq so it can be used in combination with platinum-based chemotherapy as a first line treatment for advanced urothelial cancer or urothelial cancer that has spread to other parts of the body.

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How does Tecentriq work?

The active substance in Tecentriq, atezolizumab, is a monoclonal antibody (a type of protein) designed to recognise and attach to a protein called PD-L1 (programmed death-ligand 1), which is present on many cancer cells.

PD-L1 acts to switch off immune cells that would otherwise attack the cancer cells. By attaching to PD-L1 and reducing its effects, Tecentriq increases the ability of the immune system to attack the cancer cells and thereby slow down progression of the disease.

What did the company present to support its application?

The company presented data from a main study in around 1,200 patients with advanced urothelial cancer or urothelial cancer that has spread to other parts of the body who had not been treated before. Patients received either Tecentriq plus gemcitabine in combination with carboplatin or cisplatin (both platinum therapies); placebo plus gemcitabine in combination with carboplatin or cisplatin; or Tecentriq alone. The study looked at how long patients lived before their disease got worse and how long patients lived overall.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the initial information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Tecentriq could not have been authorised for the first-line treatment of patients with urothelial cancer in combination with cisplatin.

The Agency noted that the main study could not show that Tecentriq was effective as the different types of patients involved and treatments used made interpreting the results difficult. Data on how long patients lived before their disease got worse were not conclusive and those on survival were not statistically significant (meaning that they may be due to chance).

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Tecentriq in the first-line treatment of urothelial cancer did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it withdrew its application because the Agency could not conclude on a positive benefit-risk balance based on the data provided.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that this withdrawal has no consequences for patients in clinical trials using Tecentriq.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.