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

Roche Registration GmbH withdrew its application to extend the use of Tecentriq in combination with bevacizumab for the treatment of adults with hepatocellular carcinoma (a cancer that starts in the liver), when the cancer has been removed by surgery or other techniques and is at high risk of coming back.

The company withdrew the application on 6 September 2024.

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine used to treat:

- urothelial cancer (cancer of the bladder and urinary system);
- lung cancer;
- hepatocellular carcinoma;
- a type of breast cancer known as triple-negative breast cancer;

For hepatocellular carcinoma, Tecentriq is used in combination with bevacizumab in adults whose cancer is advanced or cannot be removed by surgery and who have not previously been treated.

Tecentriq has been authorised in the EU since September 2017. It 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/en/medicines/human/EPAR/tecentriq.

What change had the company applied for?

The company had applied to extend the use of Tecentriq to adults with hepatocellular carcinoma whose cancer has been removed by surgery or other techniques and is at high risk of coming back. Tecentriq was meant to be used in combination with bevacizumab.

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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 668 patients with hepatocellular carcinoma whose cancer had been completely removed by surgery or other techniques and was at high risk of coming back. The patients either received Tecentriq with bevacizumab or had no treatment but were closely monitored. The study looked at how long patients lived before their disease came back.

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. The company had not responded to the questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the information, at the time of the withdrawal, the Agency had concerns and its provisional opinion was that Tecentriq could not have been authorised for the treatment of adults with hepatocellular carcinoma whose cancer has been removed by surgery or other techniques and is at high risk of coming back.

The Agency questioned the clinical relevance of the benefits observed with the combination treatment as compared with active surveillance of the patients, in particular in view of the safety profile of the treatment and the lack of overall survival data. Regarding safety, the Agency considered that further data were needed on the cases of death reported in the study to determine if they were linked to the combination treatment. In addition, the Agency considered that the indication should have referred to fully removed cancers to reflect more closely the patients included in the study.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Tecentriq in the treatment of hepatocellular carcinoma that has been removed by surgery or other techniques and is at high risk of coming back 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 newly available results from the main study were not sufficient to support an extension of the use of Tecentriq in combination with bevacizumab to adults with hepatocellular carcinoma whose cancer has been removed by surgery or other techniques and is at high risk of coming back.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that this withdrawal will impact two studies evaluating Tecentriq plus bevacizumab in patients with hepatocellular carcinoma whose cancer has been removed, including the main study supporting this withdrawn application. There are no consequences for patients in other clinical trials with Tecentriq.

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

What is happening with Tecentriq for the treatment of other diseases?

There are no consequences for the use of Tecentriq in its authorised uses, including the treatment of hepatocellular carcinoma in adults whose cancer is advanced or cannot be removed by surgery and has not been previously treated.