16 November 2018
EMA/798527/2018
EMEA/H/C/004143/II/0014

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

On 22 October 2018, Roche Registration GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for Tecentriq to extend its use for treating kidney cancer.

What is Tecentriq?

Tecentriq is a cancer medicine already authorised for treating urothelial carcinoma (a cancer of the bladder and urinary system) and a type of lung cancer called non-small cell lung cancer.

It contains the active substance atezolizumab and has been authorised since September 2017. Further information on Tecentriq's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/tecentriq.

What was Tecentriq expected to be used for?

Tecentriq was also expected to be used in combination with another medicine, bevacizumab, to treat a type of kidney cancer called renal cell carcinoma (RCC) when the cancer is advanced or has spread to other parts of the body.

The intended patients were to have high levels of PD-L1, a protein that the medicine uses to work against cancer cells.

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 'programmed death-ligand 1' (PD-L1), which is present on the surface of many cancer cells.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 the progression of the disease.

What did the company present to support its application?

The company presented data from a main study in 915 patients which compared Tecentriq plus bevacizumab with the cancer medicine sunitinib. The study looked at how long patients lived overall and how long they lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

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 results from the main study were not sufficient to support a new use at present. The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Tecentriq.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Tecentriq for treatment of urothelial carcinoma and lung cancer?

Tecentriq will continue to be used for treating these cancers. This withdrawal has no consequences on the medicine's currently authorised uses.