EMA/712397/2022
EMEA/H/C/005102

Tecartus (*brexucabtagene autoleucel*)

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

What is Tecartus and what is it used for?

Tecartus is a cancer medicine used to treat:

- adults with mantle cell lymphoma (a cancer of B cells, a type of white blood cell) when the cancer has come back after two or more previous treatments, including a type of cancer medicine called a Bruton's tyrosine kinase (BTK) inhibitor;
- adults 26 years of age and older with acute lymphoblastic leukaemia (another cancer of B cells) when the cancer has come back or did not respond to previous treatments.

These type of B-cell cancers are rare, and Tecartus was designated an 'orphan medicine' (a medicine used in rare diseases) for mantle cell lymphoma on 13 November 2019 and for acute lymphoblastic leukaemia on 19 October 2020.

Tecartus contains the active substance brexucabtagene autoleucel, which consists of genetically modified white blood cells.

How is Tecartus used?

Tecartus can only be obtained with a prescription. It must be given to patients by trained doctors in specialist hospitals.

Tecartus is prepared using the patient's own white blood cells which are extracted from the blood, genetically modified in the laboratory and then given back to the patient as a single infusion (drip) into a vein. Tecartus must only be given to the patient whose cells were used to make it.

Before receiving Tecartus, the patient should have a short course of chemotherapy to clear away their white blood cells, and just before the infusion the patient is given paracetamol and an antihistamine medicine to reduce the risk of reactions to the infusion.

A medicine called tocilizumab (or a suitable alternative if tocilizumab is unavailable due to a shortage), and emergency equipment must be available in case the patient has a potentially serious side effect called cytokine release syndrome (see risks section below).

Patients should be closely monitored for side effects for 10 days after treatment and are advised to stay close to a specialist hospital for at least 4 weeks after treatment.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

For more information about using Tecartus, see the package leaflet or contact your doctor or pharmacist.

How does Tecartus work?

Tecartus contains brexucabtagene autoleucel, which consist of the patient's own T cells (a type of white blood cell). These have been modified genetically in the laboratory, so that they make a protein called chimeric antigen receptor (CAR), which helps the T cells attach to a protein on the cancer cells called CD19.

When Tecartus is infused to the patient, the modified T cells can then attach to and kill the cancer cells, thereby helping to clear the cancer from the body.

What benefits of Tecartus have been shown in studies?

Mantle cell lymphoma (MCL)

A main study, which is currently ongoing, involved 74 adults with MCL whose cancer had come back after at least two previous treatments including a BTK inhibitor. Around 59% of patients (44 out of 74) treated with Tecartus had a complete response (which means they had no signs of the cancer left). This was better than results previously seen in similar patients given other treatments.

Acute lymphoblastic leukaemia (ALL)

In a main study involving 55 patients, Tecartus was shown to be effective in treating ALL that came back after or did not respond to previous treatments. After about 17 months of treatment, around 71% (39 out of 55) of patients had a complete response (no signs of cancer left) and 56% of all the patients (31 out of 55) had a complete response with their blood counts returning to normal.

What are the risks associated with Tecartus?

In the clinical study, serious side effects occurred in more than half of all patients. The most common serious side effects (which may affect more than 1 in 10 people) are cytokine release syndrome (a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, pain and low blood pressure), encephalopathy (a brain disorder with headache, sleepiness and mental confusion) and infections.

Why is Tecartus authorised in the EU?

Patients with MCL and ALL have poor outcomes, particularly if the cancers come back or did not respond to previous treatments (such as a BTK inhibitor in patients with MCL). Tecartus provides a treatment option for these patients. Although serious side effects occur in most patients and can include cytokine release syndrome, these are manageable if the appropriate measures are in place (see below). The European Medicines Agency therefore decided that Tecartus' benefits are greater than its risks and it can be authorised for use in the EU.

Tecartus has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Tecartus?

Since Tecartus has been given a conditional authorisation, the company that markets the medicine will provide to the Agency the final reports of the currently ongoing study on MCL by 2025. The company should also carry out a study on the long-term effects and safety in women, the elderly and patients who are very ill with MCL.

To obtain more information on the long-term efficacy and safety of Tecartus in patients with ALL, the company will provide follow-up data from the ongoing study and will conduct an additional study involving patients with ALL.

What measures are being taken to ensure the safe and effective use of Tecartus?

The company that markets Tecartus must ensure that hospitals where Tecartus is given have appropriate expertise, facilities and training. Tocilizumab or a suitable alternative in case tocilizumab is unavailable due to a shortage must be available in case of cytokine release syndrome. The company must provide educational materials for healthcare professionals and patients about possible side effects of Tecartus, especially cytokine release syndrome.

The company must carry out several studies to obtain more information on Tecartus including its safety and effectiveness in the long term.

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

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

Other information about Tecartus

Tecartus received a conditional marketing authorisation valid throughout the EU on 14 December 2020.

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

This overview was last updated in 08-2022.