EMA/495475/2018
EMEA/H/C/004480

Yescarta (*axicabtagene ciloleucel*)

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

What is Yescarta and what is it used for?

Yescarta is a medicine for treating two types of blood cancer:

- diffuse large B-cell lymphoma (DLBCL);
- primary mediastinal large B-cell lymphoma (PMBCL).

Yescarta is for adult patients whose blood cancer has returned or has stopped responding to previous treatment.

Yescarta is a type of advanced therapy medicine called a 'gene therapy product'. This is a type of medicine that works by delivering genes into the body.

The blood cancers that Yescarta is used to treat are rare, and Yescarta was designated an 'orphan medicine' (a medicine used in rare diseases) for DLBCL on 16 December 2014 and for PMBCL on 9 October 2015.

Yescarta contains the active substance axicabtagene ciloleucel (consisting of genetically modified white blood cells).

How is Yescarta used?

Yescarta is prepared using the patient's own white blood cells which are extracted from the blood and genetically modified in the laboratory.

It is given as a single infusion (drip) into a vein and must only be given to the patient whose cells were used to make it. Before having Yescarta, the patient should have a short course of chemotherapy to clear away their existing white blood cells, and just before the infusion they are given paracetamol and an antihistamine medicine to reduce the risk of reactions to the infusion.

A medicine called tocilizumab 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 10 days after treatment for side effects and are advised to stay close to a specialist hospital for at least 4 weeks after treatment.

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

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

How does Yescarta work?

Yescarta contains the patient's own T cells (a type of white blood cell) that have been modified genetically in the laboratory so that they make a protein called chimeric antigen receptor (CAR). CAR can attach to another protein on the surface of cancer cells called CD19.

When Yescarta is given to the patient, the modified T cells attach to and kill cancer cells, thereby helping to clear the cancer from the body.

What benefits of Yescarta have been shown in studies?

A main study of 111 patients with DLBCL and PMBCL that was not responding to previous treatment or had returned showed that Yescarta is effective at clearing the cancer in many patients. Of the patients who joined the study, 47% had a complete response (which means they had no signs of the cancer left) and 66% had at least a partial response after treatment with Yescarta.

These results were better than those from studies of patients receiving standard cancer treatments, where around 7% of patients had a complete response and around 26% had at least a partial response.

What are the risks associated with Yescarta?

Serious side effects occur in more than 1 in 2 patients. The most common serious side effects 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 caused associated with headache, somnolence and mental confusion) and infections.

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

Why is Yescarta authorised in the EU?

A main study showed that Yescarta is effective at clearing the cancer in many patients with DLBCL and PMBCL that was not responding to previous treatment or had returned. The number of patients who were cleared of the cancer or had at least a partial response was higher than in patients receiving standard care.

Serious side effects, particularly cytokine release syndrome, can occur; however these are manageable if appropriate measures are in place (see below). The European Medicines Agency therefore decided that Yescarta'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 Yescarta?

The company that markets Yescarta must ensure that hospitals where Yescarta is given have appropriate expertise, facilities and training. Tocilizumab must be available in case of cytokine release syndrome. The company must provide educational materials for healthcare professionals and patients about possible side effects, especially cytokine release syndrome.

The company must also carry out a study to obtain more information on the long term safety of Yescarta.

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

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

Other information about Yescarta

Yescarta received a marketing authorisation valid throughout the EU on 23 August 2018.

Further information on Yescarta can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.