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Breyanzi (lisocabtagene maraleucel)

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

What is Breyanzi and what is it used for?

Breyanzi is a medicine used in adults to treat different types of lymphoma (cancer of white blood cells):

- diffuse large B-cell lymphoma (DLBCL);
- high-grade B-cell lymphoma (HGBCL);
- primary mediastinal large B-cell lymphoma (PMBCL);
- follicular lymphoma (FL);
- mantle cell lymphoma (MCL).

Breyanzi is used in adults with DLBCL, HGBCL, PMBCL and FL grade 3B (FL3B; a more aggressive form of FL) whose cancer came back (relapsed) within 12 months of finishing chemoimmunotherapy, or who did not respond (refractory) to their first round of chemoimmunotherapy. Chemoimmunotherapy is a combination of systemic therapy (treatment given by mouth or injection) to kill or slow the growth of cancer cells and immunotherapy to stimulate or restore the immune system's ability to fight the cancer.

In adults with relapsed or refractory DLBCL, PMBCL, FL3B or FL, Breyanzi can also be used after two or more previous treatments with systemic therapy.

In adults with MCL, Breyanzi is used in patients whose cancer has come back or who did not respond after at least two systemic therapies including a Bruton's tyrosine kinase inhibitor, a type of cancer medicine.

Breyanzi contains lisocabtagene maraleucel, which is a combination of two types of genetically modified white blood cells.

How is Breyanzi used?

Breyanzi is prepared using the patient's own white blood cells. These are extracted from the patient's blood, genetically modified in a laboratory, and then given back to the patient.

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The medicine is given as a single infusion (drip) into a vein. Before treatment with Breyanzi, the patient should have a short course of systemic chemotherapy to clear away their existing white blood cells, and just before the infusion they should be given other medicines to reduce the risk of adverse reactions to the infusion.

A medicine called tocilizumab (or a suitable alternative if this 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 one week after treatment and are advised to stay close to a specialist hospital for at least 2 weeks after treatment.

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

How does Breyanzi work?

Breyanzi contains lisocabtagene maraleucel, which is a combination of two types of white blood cells (CD4+ T cells and CD8+ T cells) collected from the patient. These cells have been genetically modified in the laboratory to make a protein called chimeric antigen receptor (CAR). CAR can attach to CD19, a protein that is found on the surface of cancer cells.

When Breyanzi is given to the patient, the modified cells attach to CD19 proteins on the cancer cells and kill them, thereby helping to clear the cancer from the body.

What benefits of Breyanzi have been shown in studies?

Benefits of Breyanzi were shown in two main studies involving more than 300 adult patients with DLBCL that had not responded to previous treatment or had returned after at least two courses of therapy or after a stem cell transplant. These studies showed that 53% and 33% of patients treated with Breyanzi had a complete response (meaning that they had no signs of cancer after treatment) and 73% and 61% had at least a partial response (a decrease in the extent of the cancer in the body). Comparable responses were seen in an analysis of a smaller number of patients with PMBCL and FL3B in these studies. These results were at least as good as the results seen in other studies involving patients receiving standard cancer treatments.

Another main study involved 184 patients with large B-cell lymphomas (DLBCL, HGBCL, PMBCL and FL3B) that had returned shortly after, or did not respond to, first-line immunochemotherapy. Patients were given Breyanzi or standard treatment, and the study looked at the time until patients experienced certain outcomes (an 'event', meaning their treatment did not work after 9 weeks, they started a different treatment because the treating doctor considered the current medicine ineffective, their cancer worsened or they died). The study showed that patients given Breyanzi lived longer without experiencing an event: 10.1 months, on average, for patients given Breyanzi compared with 2.3 months for patients given standard treatment. In addition, after 6 months, 66% of patients given Breyanzi had had a complete response compared with 39% of those who received standard treatment.

Another main study involved 103 patients with FL that had come back or not responded to two previous treatments with systemic therapy. The study did not compare Breyanzi with placebo (a dummy treatment) or another medicine. In this study, 97% (100 of 103) of patients responded to treatment with Breyanzi, including 94% (97 out of 103) who had a complete response.

In another main study, 88 adults with MCL whose cancer had come back or not responded to at least 2 therapies, including a BTK inhibitor, received Breyanzi. No patients received another treatment or

placebo. Around 83% (67 out of 81) of patients responded at least partially to treatment with Breyanzi, with around 72% of patients (58 out of 81) having a complete response. The responses lasted around 11 months on average.

What are the risks associated with Breyanzi?

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

The most common side effects with Breyanzi (which may affect more than 1 in 10 people) in patients with large B-cell lymphomas who had received one previous treatment with systemic therapy include cytokine release syndrome (a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, pain and low blood pressure), neutropenia (low blood levels of neutrophils, a type of white blood cell that fights infection), anaemia (low levels of red blood cells) and thrombocytopenia (low levels of blood platelets, components that help the blood to clot). In patients with large B-cell lymphomas who received two or more previous treatments with systemic therapy, more than 1 in 10 people experienced cytokine release syndrome, neutropenia, anaemia, thrombocytopenia and fatigue (tiredness).

In patients with FL who received two or more previous treatments with systemic therapy the most common side effects (which may affect more than 1 in 10 people) include neutropenia, cytokine release syndrome, anaemia, headache, thrombocytopenia and constipation.

In patients with MCL, the most common side effects (which may affect more than 1 in 10 people) include cytokine release syndrome, neutropenia, anaemia, tiredness, thrombocytopenia and headache.

Some side effects may be serious. In patients with large B-cell lymphomas who previously received a single course of treatment, the most frequent serious side effects include cytokine release syndrome (which may affect more than 1 in 10 people), as well as neutropenia, anaemia, thrombocytopenia, neutropenia with fever, fever, infections, aphasia (problems with the use of language), headache, confusion, pulmonary embolism (a blood clot in a blood vessel in the lungs), upper gastrointestinal (stomach and gut) haemorrhage (bleeding) and tremor (shaking), which may all affect up to 1 in 10 people.

In patients with large B-cell lymphomas who previously received two or more previous treatments with systemic therapy, the most frequent serious side effects include cytokine release syndrome (which may affect more than 1 in 10 people) as well as neutropenia, anaemia, thrombocytopenia, neutropenia with fever, fever, infections, encephalopathy (a brain disorder caused by infection), aphasia, confusion, tremor and hypotension (low blood pressure), which may all affect up to 1 in 10 people.

In patients with FL who received two or more previous treatments with systemic, therapy the most frequent serious side effects (which may affect up to 1 in 10 people) include cytokine release syndrome, aphasia, neutropenia with fever, fever and tremor.

In patients with MCL, the most frequent serious side effects include cytokine release syndrome (which may affect more than 1 in 10 people), as well as confusion, fever, mental status changes, encephalopathy, upper respiratory tract infection and pleural effusion (fluid around the lungs), which may all affect up to 1 in 10 people.

Why is Breyanzi authorised in the EU?

Breyanzi was shown to be at least as effective as existing treatment options in patients with relapsed or refractory DLBCL, PMBCL and FL3B who had received at least two previous treatments. Breyanzi

also showed benefits in patients with large B-cell lymphomas whose cancer had returned shortly after, or who did not respond to, one previous treatment.

The medicine also showed benefits in patients with FL that had come back or not responded to at least two previous treatments with systemic therapy. However, there were some uncertainties due to the small number of patients in the main study as well as the lack of a comparator.

In MCL, Breyanzi was shown to provide durable benefits in patients whose cancer was resistant or had come back after at least 2 previous treatments; these patients have very few effective treatment options.

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 the benefits of Breyanzi 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 Breyanzi?

The company that markets Breyanzi must ensure that hospitals where Breyanzi is given have appropriate expertise, facilities and training. Tocilizumab, or suitable alternatives if it is unavailable due to a shortage, must be available for the management 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 provide additional data from ongoing and future studies to further characterise the long-term safety and effectiveness of Breyanzi.

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

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

Other information about Breyanzi

Breyanzi received a marketing authorisation valid throughout the EU on 4 April 2022.

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

This overview was last updated in 11-2025.