swissmedic

Summary report on authorisation dated 21 November 2025

Breyanzi® (active substance: lisocabtagene maraleucel)

Indication extension in Switzerland: 2 June 2025

Dispersion for infusion for the treatment of adults with relapsed or refractory follicular lymphoma (r/r FL) after at least two prior therapies

About the medicinal product

The medicinal product Breyanzi, containing the active substance lisocabtagene maraleucel, is an immunotherapy containing genetically modified autologous T cells. It is administered as an intravenous infusion.

Swissmedic first authorised Breyanzi on 28 February 2022 for the treatment of adults with specific types of blood cancer called "diffuse large B-cell lymphoma" (DLBCL) and "primary mediastinal large B-cell lymphoma" (PMBCL) after at least two prior therapies.

As a result of this indication extension of 2 June 2025, Breyanzi is now also authorised for the treatment of adults with another specific type of blood cancer called "relapsed or refractory follicular lymphoma" (r/r FL). In this disease, B cells[1] multiply uncontrolled and accumulate in the lymph nodes. Patients to be treated with Breyanzi must have undergone at least two previous systemic therapies[2], despite which their cancer has recurred (relapsed) or progressed (become refractory).

Since DLBCL, PMBCL and FL are rare and life-threatening diseases, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

[1] B cells: A type of white blood cell that forms part of the immune system. B cells identify pathogens and form antibodies to specifically combat them.

[2] Systemic therapy: In contrast to local therapy (treatment at the site of the disorder), systemic therapy involves treatment of the entire body to eliminate a disorder.

Mode of action

The active substance lisocabtagene maraleucel is what is called a CD19-directed cellular immunotherapy (CAR-T cell therapy[3]). This involves genetically modified immune cells from the patient's own body (CAR-T cells) binding specifically to the CD19 antigen on the surface of B-cells.

As they bind, they trigger downstream signals, thereby activating the CAR-T cells and causing them to multiply.

As a result, the body's own immune system is able to destroy the abnormal B-cells that cause the cancer.

Administration

Breyanzi, containing the active substance lisocabtagene maraleucel, is a prescription-only medicine.

The medicinal product Breyanzi is a dispersion for infusion containing CAR-positive viable T cells. Each vial contains 4.6 ml of cell suspension with an equal proportion of CD8 and CD4 cell components[4] and is injected intravenously.

The recommended target dose of Breyanzi is 100 million CAR-T cells.

Treatment with Breyanzi is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments.

Before receiving treatment with Breyanzi, patients are pretreated with chemotherapy.

Before using Breyanzi, the doctor will give the patient suitable medicines to minimise possible infusion reactions.

The therapy is administered in a treatment centre with direct access to appropriate intensive care units for the treatment of possible severe reactions.

Efficacy

The efficacy of Breyanzi was investigated in the TRANSCEND FL trial in adults with relapsed or refractory follicular lymphoma (r/r FL) who had previously received at least two lines of systemic therapy. A total of 130 patients who were included in the efficacy analysis received an infusion of Breyanzi.

The primary endpoint of the trial was overall response rate (ORR)[5], which was 97%, while the secondary endpoint of complete response rate (CRR)[6] was 94%. The median follow-up period[7] was around 30 months, sufficient time to assess the long-term effects of

[3] CAR-T cell therapy: A specific cancer immunotherapy in which the patient's own immune cells are collected and genetically modified so they can recognise and specifically destroy cancer cells. The modified T cells (CAR-T) cells are administered to the patient by infusion.

[4] CD4 and CD8 cells: CD4 ("helper") and CD8 ("killer") T cells are different immune cells in the immune system. The CD4 cells support and activate the CD8 cells, which specifically destroy the cancer cells. Both types of cell are required for effective, long-lasting treatment.

[5] Overall response rate (ORR): The percentage of patients who respond to the treatment.

[6] Complete response rate (CRR): The percentage of patients in whom no signs of disease can be detected after treatment.

[7] Median follow-up period: The average time during which the patients in a trial are followed-up/observed. Half the patients were observed for a shorter period, half for a longer period.

the medicine and confirm its continuing efficacy.

Precautions, undesirable effects, & risks

The medicinal product Breyanzi must not be used in those who are hypersensitive to the active substance or any of the excipients.

Breyanzi may only be used in patients with relapsed or refractory follicular lymphoma (r/r FL) after possible infections or unresolved side effects of preceding treatments have been carefully excluded. The medicinal product may cause serious adverse reactions that require immediate medical treatment.

The most common undesirable effects of any grade in patients with r/r FL who received Breyanzi (affecting more than 1 in 10 users / more than 10%) were a lack of certain white blood cells (neutropenia)[8] (68%), inflammatory response of the immune system (cytokine release syndrome, CRS[9]; 58%), anaemia (40%), headaches (29%), reduced blood platelet count (29%) and constipation (21%).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Breyanzi offers patients with relapsed or refractory follicular lymphoma (r/r FL) who have already undergone several unsuccessful attempts to treat their disease a promising option for the treatment of this serious and potentially life-threatening condition.

The clinical benefit of Breyanzi was demonstrated in the TRANSCEND-FL trial, particularly in the high overall response rate (ORR) and complete response rate (CRR).

Potential side effects, such as cytokine release syndrome (CRS), are generally controllable and treatable.

Taking all the risks and precautions into account, and based on the available data, the benefits of this treatment outweigh the risks.

Swissmedic has therefore authorised the indication extension for Breyanzi for the treatment of adults with relapsed or refractory follicular lymphoma (r/r FL) after at least two prior therapies in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Breyanzi®

Information for patients (package leaflet): Information for patients Breyanzi®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

[8] Neutropenia: Reduced count of a specific group of white blood cells.

[9] CRS: Cytokine release syndrome is a systemic inflammatory response to the massive secretion of cytokines (proteins), which activate the white blood cells.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.