swissmedic

Summary report on authorisation dated 13 December 2024

Tecartus® (active substance: brexucabtagene autoleucel)

Indication extension in Switzerland: 12 January 2023

Cell dispersion for infusion in adults for the gene therapy of relapsed or refractory acute B-cell precursor lymphoblastic leukaemia (B-ALL) (third-line treatment)

About the medicinal product

Tecartus contains the active substance brexucabtagene autoleucel and is a gene therapy medicinal product. It is used to treat adults with acute B-cell precursor lymphoblastic leukaemia (B-ALL).

Tecartus is used if the disease occurs again after two or more lines of systemic therapy (relapsed disease) or does not respond to treatment (refractory disease).

The active substance brexucabtagene autoleucel consists of the patient's own T-cells that have been modified. They have been genetically modified to specifically recognise and fight cancer cells. Infusion of these modified T-cells is intended to kill the cancer cells, which can control or improve the disease.

Tecartus was already authorised by Swissmedic on 25 August 2021 as a third-line treatment for the gene therapy of adults with relapsed or refractory mantle cell lymphoma.

Since B-ALL is a rare and life-threatening disease, the indication extension for the medicinal product has also been authorised as an "orphan drug". The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

The active substance brexucabtagene autoleucel is a so-called CD19-directed cellular immunotherapy (CAR T-cell therapy[1]). The active substance brexucabtagene autoleucel binds to the CD19 antigen on the surface of tumour cells. This binding triggers downstream signals, thereby activating the CAR T-cells and causing them to multiply.

[1] CAR T-cell therapy is a specific immunotherapy for cancer in which the patients' own immune cells are taken and modified using gene technology so that they recognise cancer cells and specifically destroy them. The modified CAR T-cells are administered to the patient via an infusion.

As a result of this mechanism of action, the body's immune system is able to fight and kill the lymphoma cells that cause the cancer.

Use

Tecartus is a prescription-only medicine.

Tecartus is a patient-specific anti-CD19-CAR T-cell dispersion for infusion into a vein.

It is administered in the following steps. First, the patient's T-lymphocytes (a subgroup of white blood cells) are collected. These cells are then used to produce the CAR T-cells individually for each patient. Before Tecartus is administered, the number of lymphocytes in the blood and bone marrow must be reduced by chemotherapy. The CAR T-cell infusion is then administered directly afterwards.

The therapy is administered in a treatment centre with immediate access to appropriate intensive care units for the treatment of possible severe reactions. The patients should visit the hospital daily for at least 10 days after the Tecartus treatment or remain in hospital as inpatients, and then stay within reach of the treating hospital for at least 4 weeks.

Efficacy

The efficacy of Tecartus in the therapy of adults with acute B-cell precursor lymphoblastic leukaemia (B-ALL) was investigated in the ZUMA-3 trial with 71 male and female patients with relapsed or refractory ALL.

The primary endpoint of the trial was the overall complete remission rate (OCR) comprising complete remission (CR) and complete remission with incomplete haematological recovery (CRi). In this context, remission means a decrease in or the disappearance of the disease or its symptoms. Incomplete haematological recovery means that the healthy functioning of the blood has been partly restored.

The results show an OCR rate of 66.7% and a CR rate of 51.1%.

The median[2] duration of the remission was 14.6 months.

Precautions, undesirable effects, & risks

Tecartus must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent adverse effects are infections (28%), encephalopathy (disease of the brain) (26%), and cytokine release syndrome (CRS)[3] (15%).

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

[2] Median: the value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

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

When the indication extension for Tecartus was authorised, there was a high level of unmet medical need for adults with relapsed or refractory B-ALL.

The ZUMA-3 trial showed that 66.7% of the patients treated with Tecartus achieved either a complete remission (CR) or a complete remission with incomplete haematological recovery (CRi). Furthermore, another trial (retrospective SCHOLAR-3) confirmed that patients who have been treated with Tecartus have a significantly higher survival rate compared to historical controls. The benefit of Tecartus outweighs the risks associated with CRS and neurological side effects for this difficult-to-treat group of patients. On the basis of these findings, Swissmedic has also authorised the medicinal product Tecartus, containing the active substance brexucabtagene autoleucel, for Switzerland with the present indication extension for the treatment of adults with relapsed or refractory acute B-cell precursor lymphoblastic leukaemia (B-ALL).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tecartus®

Information for patients (package leaflet): Information for patients Tecartus®

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.

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