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Public Summary SwissPAR dated 27 September 2024

Ebvallo® (active substance: tabelecleucel)

Authorisation in Switzerland: 3 May 2024

Dispersion for injection for the treatment of adults and children aged 2 years and older with relapsed or refractory Epstein-Barr virus-positive post-transplant lymphoproliferative disorder

About the medicinal product

Ebvallo contains the active substance tabelecleucel. Ebvallo is a medicinal product for the treatment of adults and children aged 2 years and older who develop a blood cancer known as "Epstein-Barr virus-positive post-transplant lymphoproliferative disorder" (EBV+ PTLD) following an organ or bone marrow transplant.

Tabelecleucel consists of cells from the immune system, known as T cells, that have been taken from a donor. The T cells are first mixed with B cells from the same donor, which have been infected with Epstein-Barr virus, so that the T cells learn to recognise infected B cells as "foreign". When the medicinal product is then given to the patient, the T cells attack and kill the patient's own infected B cells, thereby helping to control the EBV+ PTLD.

EBV+ PTLD is a severe complication that may occur following an organ or stem cell transplant that can lead to a blood cancer (PTLD). Due to the need to use medications that suppress the immune system during transplant procedures, Epstein-Barr virus infections of the body's own immune cells (EBV+) can occur. These infections can then lead to cancer.

Ebvallo is used in patients who have received at least 1 prior treatment when the illness recurs (relapsing) or when the treatment was not effective (refractory).

Since EBV+ PTLD is a rare and life-threatening disease, the medicinal product Ebvallo has been authorised as an "orphan drug". The term "orphan drug" is used to refer to important medicines for rare diseases.

Ebvallo has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made

available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Ebvallo in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/858618/2022) and has only conducted a limited scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ebvallo®

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

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 Public Summary SwissPAR.

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.