13 October 2022
EMA/CHMP/791184/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ebvallo

tabelecleucel

On 13 October 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Ebvallo[3], intended for the treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV^+ PTLD). As Ebvallo is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies.

The applicant for this medicinal product is Atara Biotherapeutics Ireland Limited.

Ebvallo will be available as a dispersion for injection containing $2.8 \times 10^7 – 7.3 \times 10^7$ viable T cells/mL. The active substance of Ebvallo is tabelecleucel, an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in a human leukocyte antigen (HLA)-restricted manner.

The benefit of Ebvallo is its ability to bring about a response in patients with relapsed and refractory EBV^+ PTLD. The most common side effects are pyrexia, diarrhoea, fatigue, nausea, anaemia, decreased appetite and hyponatraemia.

The full indication is:

> Ebvallo is indicated as monotherapy for treatment of adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

Ebvallo should be prescribed by physicians experienced in the treatment of cancer.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.