15 October 2020
EMA/CHMP/538747/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tecartus

autologous anti-CD19-transduced CD3+ cells

On 15 October 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Tecartus[2], intended for the treatment of relapsed or refractory mantle cell lymphoma (MCL). As Tecartus 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 Kite Pharma EU B.V.

Tecartus is an autologous T-cell immunotherapy which will be available as a dispersion for infusion (0.4–2.0 x 10^8 cells). The active substance in Tecartus is genetically modified autologous anti-CD19-transduced CD3+ cells. By binding to CD19-expressing cancer cells and normal B cells, the medicine starts T-cell activation and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

The benefit of Tecartus is the tumour shrinkage (response) of mantle cell lymphoma which had relapsed or was refractory to other treatment. The most common side effects are cytokine release syndrome, infections and encephalopathy.

The full indication is:

> Tecartus is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.

Tecartus should be prescribed by physicians experienced in the treatment of mantle cell lymphoma and must be administered in a qualified treatment centre by a physician with experience in the treatment of haematological malignancies and trained for administration and management of patients treated with Tecartus.

[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] 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

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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.