28 June 2018
EMA/CHMP/396710/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yescarta

axicabtagene ciloleucel

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yescarta, intended for the treatment of diffuse large cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL). As Yescarta is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies.

Yescarta, which was designated as an orphan medicinal product on 16 December 2014, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Kite Pharma EU B.V.

Yescarta will be available as a dispersion for infusion. The active substance of Yescarta is axicabtagene ciloleucel, an autologous, immunocellular cancer therapy which involves reprogramming a patient's own T cells to identify and eliminate CD19-expressing cells. This is achieved by addition of a transgene encoding a chimeric antigen receptor (CAR).

The benefits with Yescarta are its ability to achieve an objective response with a significant duration in patients with DLBCL and patients with PMBCL. The most common side effects are cytokine release syndrome, infections, pyrexia, diarrhoea, nausea, hypotension and fatigue.

The full indication is:

> "Yescarta is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy."

It is proposed that Yescarta be administered in a qualified treatment centre. Therapy should be started and supervised by a healthcare professional experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with Yescarta.

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

[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

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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.