EMA/CHMP/289459/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kymriah

tisagenlecleucel

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 Kymriah, intended for the treatment of acute lymphoblastic leukaemia (ALL) and diffuse large B-cell lymphoma (DLBCL). As Kymriah is an advanced therapy medicinal product, the CHMP positive opinion is based on an assessment by the Committee for Advanced Therapies.

Kymriah, which was designated as an orphan medicinal product on 29 April 2014, was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Novartis Europharm Limited.

Kymriah will be available as a dispersion for infusion. The active substance of Kymriah is tisagenlecleucel, 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 of Kymriah are its ability to achieve remission with a significant duration in patients with ALL and to achieve an objective response with a significant duration in patients with DLBCL. The most common side effects in patients with ALL are cytokine release syndrome, infections, hypogammaglobulinaemia, pyrexia and decreased appetite. The most common side effects in patients with DLBCL are cytokine release syndrome, infections, pyrexia, diarrhoea, nausea, hypotension and fatigue.

The full indication is:

> "Kymriah is indicated for the treatment of:
>
> Paediatric and young adult patients up to 25 years of age with B-cell acute lymphoblastic leukaemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse.
>
> Adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy."

[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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It is proposed that Kymriah 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 Kymriah.

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.