22 May 2025
EMA/CHMP/165911/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aucatzyl

obecabtagene autoleucel

On 22 May 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Aucatzyl[3], intended for the treatment of adults from 26 years of age with relapsed or refractory B cell precursor acute lymphoblastic leukaemia.

As Aucatzyl 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 Autolus GmbH.

Aucatzyl will be available as a 410 x 10^6 cells dispersion for infusion. The active substance of Aucatzyl is obecabtagene autoleucel, an antineoplastic cell and gene therapy (ATC code: L01XL12). Aucatzyl is an autologous immunotherapy consisting of the patient's own T cells engineered to express a chimeric antigen receptor that recognises and binds to CD19 on target cells. This results in activation of the immunological effect of the T-cell releasing inflammatory cytokines and chemokines, leading to killing of CD19-expressing cells.

The benefits of Aucatzyl are its ability to induce remission with a relevant duration in adults with relapsed or refractory acute lymphoblastic leukaemia, as seen in an open-label, multi-centre, single arm phase Ib/II study. The most common side effects with Aucatzyl include cytokine release syndrome, infections, musculoskeletal pain, pyrexia, pain, nausea, diarrhoea, headache, fatigue and haemorrhage.

The full indication is:

> Aucatzyl is indicated for the treatment of adult patients 26 years of age and above with relapsed or refractory (r/r) B cell precursor acute lymphoblastic leukaemia (B ALL).

Aucatzyl must be administered in a qualified treatment centre by a physician with experience in the

[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] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[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

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treatment of haematological malignancies and trained for administration and management of patients treated with the medicinal product.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.