EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2025
EMA/CHMP/189609/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zemcelpro

dorocubicel / allogeneic umbilical cord-derived CD34- cells, non-expanded

On 19 June 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 Zemcelpro[3], intended for the treatment of adults with haematological malignancies requiring an allogeneic haematopoietic stem cell transplantation for whom no other type of suitable donor cells is available.

As Zemcelpro 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 Cordex Biologics International Limited.

The two active substances of Zemcelpro, dorocubicel and non-expanded CD34- cells are stem cells from umbilical cord blood (ATC code: B05AX04). Dorocubicel consists of CD34+ cells expanded ex-vivo. Zemcelpro will be available as a ≥0.23 x 10^6 viable CD34+ cells/ml / ≥0.53 x 10^6 viable CD3+ cells/ml dispersion for infusion. Once infused to the patient, the cells from Zemcelpro migrate to the bone marrow where they divide, mature and differentiate in all haematological cell lineages.

The benefit of Zemcelpro is its ability to induce neutrophil and platelet engraftment, as observed in two single-arm, open label, phase 2 clinical studies. The most common side effects with Zemcelpro include lymphopenia, infections, anaemia, neutropenia, thrombocytopenia, leukopenia, hypogammaglobulinaemia, febrile neutropenia, hypertension, engraftment syndrome, pneumonia, and graft-versus-host disease (GvHD).

The full indication is:

> Zemcelpro is indicated for the treatment of adult patients with haematological malignancies requiring an allogeneic haematopoietic stem cell transplantation following myeloablative

[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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conditioning for whom no other type of suitable donor cells is available.

Zemcelpro should be administered in a qualified transplant centre with expertise in haematopoietic stem cell transplant by a physician with experience in the treatment of haematological malignancies.

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.