27 February 2025
EMA/CHMP/52904/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vyjuvek

beremagene geperpavec

On 27 February 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vyjuvek[2], intended for the topical treatment of wounds in people with dystrophic epidermolysis bullosa caused by mutations in the collagen type 7 alpha 1 chain (*COL7A1*) gene. As Vyjuvek 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 Krystal Biotech Netherlands, B.V.

Vyjuvek will be available as 5 x 10^9 plaque forming units/ml suspension and gel for gel. The active substance of Vyjuvek is beremagene geperpavec, a cicatrisant preparation for the treatment of wounds and ulcers (ATC code: D03AX16). Vyjuvek is a gene therapy based on a herpes simplex virus 1, genetically modified to be replication-defective and encode the *COL7A1* gene. When the gel is applied to the wounds, it can transduce both keratinocytes and fibroblasts. Inside the nucleus of these cells, *COL7A1* is transcribed without integration in the patient's genome. The resulting transcripts allow for production and secretion of functional COL7 by the cells. COL7 proteins arrange themselves to form anchoring fibrils, which hold the epidermis and dermis together and are essential for maintaining the integrity of the skin.

The benefit of Vyjuvek is a higher rate of complete wound healing up to 6 months of treatment compared with placebo. The most common side effects are cough, rhinorrhoea, skin and subcutaneous tissue disorders (pruritus, erythema, rash), and chills.

The full indication is:

> Vyjuvek is indicated for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene, from birth.

[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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Vyjuvek should be initiated by healthcare professionals experienced in the management of patients with dystrophic epidermolysis bullosa.

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.