24 February 2022
EMA/CHMP/116411/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kimmtrak

tebentafusp

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kimmtrak[2], intended for the treatment of uveal melanoma.

Kimmtrak was reviewed under EMA's accelerated assessment programme.

The applicant for this medicinal product is Immunocore Ireland Limited.

Kimmtrak will be available as a 100 mcg/0.5 mL concentrate for solution for infusion. The active substance of Kimmtrak is tebentafusp, an antineoplastic agent (ATC code: L01) with bispecific affinity, targeting the CD3 T cells and a gp100 peptide on the surface of uveal melanoma tumour cells. This redirects and activates T cells and results in direct lysis of uveal melanoma tumour cells.

The benefits of Kimmtrak are a gain in median overall survival of 5.7 months over the investigator's choice treatment as observed in a randomised, open label, multicentre pivotal study. The most common side effects are cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, oedema, hypo/hyperpigmentation, hypotension, dry skin, headache and vomiting.

The full indication is:

> Kimmtrak is indicated as monotherapy for the treatment of human leukocyte antigen (HLA) A*02:01 positive adult patients with unresectable or metastatic uveal melanoma.

Kimmtrak should be administered under the direction and supervision of a physician experienced in the use of anti-cancer agents and who is prepared to manage cytokine release syndrome in an environment where full resuscitation facilities are immediately available.

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

[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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