20 July 2023
EMA/323969/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Talvey

talquetamab

On 20 July 2023, 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 Talvey[3], intended for the treatment of multiple myeloma. Talvey was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Janssen-Cilag International N.V.

Talvey will be available as a 2 mg/ml and 40 mg/ml solution for injection. The active substance of Talvey is talquetamab, a bispecific antibody that targets the CD3 receptor expressed on the surface of T cells and GPRC5D which is expressed on the surface of plasma cells, including malignant multiple myeloma cells.

The benefit of Talvey is its ability to bring about a partial or complete response in patients with relapsed or refractory multiple myeloma, as shown in a phase 1/2, open-label, dose escalation study. The most common side effects are cytokine release syndrome, dysgeusia, hypogammaglobulinaemia, nail disorder, musculoskeletal pain and anaemia.

The full indication is:

> Talvey is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Treatment should be initiated and supervised by physicians experienced in the treatment of multiple myeloma.

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.