24 March 2022
EMA/CHMP/168651/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Carvykti

ciltacabtagene autoleucel

On 24 March 2022, 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 Carvykti[3], intended for the treatment of adult patients with relapsed and refractory multiple myeloma. As Carvykti 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 Janssen-Cilag International NV.

Carvykti will be available as 3.2 x 10^6 to 1.0 x 10^8 cells dispersion for infusion.

The active substance of Carvykti is ciltacabtagene autoleucel, a genetically modified autologous T cell immunotherapy consisting of modified T-cells bearing a chimeric antigen receptor (CAR) targeting B-cell maturation antigen (BCMA). BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B cells and plasma cells. Upon binding to BCMA-expressing cells, the CAR promotes T cell activation, expansion, and elimination of target cells.

The benefits of Carvykti are a high and durable response in patients with relapsed and refractory multiple myeloma. The most common side effects are neutropenia, cytokine release syndrome, pyrexia, thrombocytopenia, anaemia, leukopenia, lymphopenia, musculoskeletal pain, hypotension, fatigue, transaminase elevation, upper respiratory tract infection, diarrhoea, hypocalcaemia, hypophosphataemia, nausea, headache, cough, tachycardia, chills, encephalopathy, decreased appetite, oedema and hypokalaemia.

The full indication is:

> CARVYKTI is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory

[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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agent, a proteasome inhibitor and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.

Carvykti should be prescribed by physicians experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with Carvykti.

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 granted by the European Commission.