EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/CHMP/348641/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abecma

idecabtagene vicleucel

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Abecma,[2] intended for the treatment of relapsed and refractory multiple myeloma. As Abecma is an advanced therapy medicinal product, the CHMP's positive opinion is based on an assessment by the Committee for Advanced Therapies.

The applicant for this medicinal product is Celgene Europe BV.

Abecma will be available as a 260-500 x 10^6 CAR-positive viable T cells dispersion for infusion. The active substance of Abecma is idecabtagene vicleucel, a chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. Antigen-specific activation of Abecma results in CAR-positive T cell proliferation, cytokine secretion and subsequent cytolytic killing of BCMA-expressing cells.

The benefits of Abecma are its ability to provide durable responses in patients with relapsed and refractory multiple myeloma. The most common side effects are neutropenia, cytokine release syndrome (CRS), anaemia, thrombocytopenia, unspecified infections, leucopenia, fatigue, diarrhoea, hypokalaemia, hypophosphataemia, nausea, lymphopenia.

The full indication is:

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

Abecma should be prescribed by physicians experienced in the treatment of haematological malignancies including multiple myeloma.

[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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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.