FDA approves Abecma for relapsed, refractory multiple myeloma

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The U.S. Food and Drug Administration has approved Abecma (idecabtagene vicleucel) as a personalized CAR T-cell therapy for triple-class exposed relapsed or refractory multiple myeloma.

The approval is for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy,

including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Abecma is a one-time infusion, with a new recommended dose range of 300 to 510 x 10^6 CAR-positive T cells.

Boxed warnings for Abecma include cytokine release syndrome, neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, prolonged cytopenia, and secondary hematological malignancies.

The approval was based on data from the Phase III KarMMa-3 trial of 254 patients. At a median follow-up of 15.9 months, Abecma more than tripled the primary end point of progression-free survival versus standard regimens, with a median progression-free survival of 13.3 months versus 4.4 months (hazard ratio, 0.49).

Overall response rates were also significantly improved with Abecma, with 71% of patients treated with Abecma achieving a response and 39% achieving a complete or stringent complete response compared with 42 and 5%, respectively, of those receiving standard regimens. Responses to Abecma were durable, with a median duration of response of 14.8 months (or 20 months for patients who derived a complete response or better).

"With this approval, these patients now have an opportunity to be treated at an earlier line of therapy with a potentially transformative therapy that offers significantly improved progression-free survival for this difficult-to-treat disease that has had no established treatment approach," Al-Ola A. Abdallah, M.D., chair of the U.S. Myeloma Innovations Research Collaborative, said in a statement.

Approval of Abecma was granted to Bristol Myers Squibb and 2seventy bio.

More information: Press Release