FILTER NEWS

- All (809,510)
- Topic (767,455)
- Hotbed/Location (737,488)
- Career Advice (3,903)
- Insights (180)
- Webinars (8)
- Podcasts (40)

# FDA Greenlights BMS, J&J CAR-T Therapies for Earlier Multiple Myeloma Treatment

Published: Apr 06, 2024 | By Heather McKenzie and Nadia Bey


*Pictured: Johnson & Johnson's office in Spain/iStock, **BrasilNut1**, BMS sign on a building in San Diego, California/iStock, **JHVEPhoto**. Collage by Nicole Bean for* BioSpace

The FDA has approved two CAR-T cell therapies for the earlier treatment of multiple myeloma. The **first approval**, for **Bristol Myers Squibb** and 2seventy Bio's Abecma, came Thursday, followed by that of **Johnson & Johnson** and **Legend Biotech**'s Carvykti on Friday.

The approvals come three weeks after an FDA advisory committee unanimously

**recommended** Carvykti as a second-line treatment for patients with refractory multiple myeloma, and backed Abecma by a vote of 8-3 for patients who had received at least two previous drug regimens. Carvykti joins seven other therapies that can be used as second-line treatments for multiple myeloma if initial therapies fail.

Both Abecma and Carvykti reprogram a patient's T-cells to eliminate cells that express B-cell maturation antigen (BCMA), which is present in normal B-cells but **overexpressed** in multiple myeloma.

While the FDA's Oncologic Drugs Advisory Committee **expressed concerns** about higher rates of early deaths in the treatment arms of trials for both drugs, it ultimately determined that the benefits of the therapies outweighed the risks.

Prior to Thursday's approval, Abecma was authorized to treat patients with relapsed or refractory multiple myeloma in adult patients who have previously received four or more treatment regimens. It is the first CAR T cell therapy approved for earlier use for triple-class exposed relapsed and/or refractory multiple myeloma, according to BMS.

"Abecma has demonstrated a progression-free survival benefit three times that of standard

regimens in relapsed or refractory multiple myeloma," Bryan Campbell, senior vice president and head of commercial, cell therapy at BMS, said in a statement.

In the Phase III KarMMa-3 trial, treatment with Abecma led to a 51% reduction in the risk of disease progression or death. Patients treated with the CAR-T therapy survived a median 13.3 months without progression, while those in the control group lived only 4.4 months without their disease advancing. Abecma's safety profile was well-established, according to BMS, though the therapy does come with a boxed warning for cytokine release syndrome, neurologic toxicities, HLH/MAS, prolonged cytopenia and secondary hematologic malignancies.

The FDA nod comes three weeks after the European Commission **authorized** Abecma for the third-line treatment of multiple myeloma.

## Carvykti Wins Second Line Nod

Carvykti, which won expanded approval late Friday evening, is the first BCMA-Targeted therapy for the second-line treatment of multiple myeloma, **according to** Legend Biotech.

The CAR-T cell therapy is authorized for patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent and are refractory to lenalidomide.

J&J and Legend Biotech supported their application with data from the CARTITUDE-4 study, where treatment with Carvykti led to "statistically significant and clinically meaningful improvement of progression-free survival compared to two standard of care treatment regimens," according to the companies.

Carvykti was also tagged with a boxed warning for potential side effects, including cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome and secondary malignancies, including myelodysplastic syndrome, acute myeloid leukemia and T-cell cancers.

The therapy was originally **approved** in February 2022 as a fifth-line treatment. It was also **conditionally approved** in Europe for patients who had tried at least three other therapies. The European Medicines Agency's Committee for Medicinal Products for Human Use recently **supported** approving Carvykti as a second-line treatment for multiple myeloma.

The FDA has demonstrated caution toward CAR-T therapies in recent months. In

November 2023, the agency **began investigating** the "serious risk" of T-cell malignancies in patients treated with BCMA- or CD19-directed autologous CAR-T cell immunotherapies. In January 2024, the FDA **called for boxed warnings** for all currently marketed CAR-T therapies after **three of 22 cases** were found to have likely causal links. However, the regulator **stated** that the overall risk of T-cell cancers in people receiving CAR-T therapies "appears to be quite low."

*Heather McKenzie is a senior editor at* BioSpace*. You can reach her at* ***heather.mckenzie@biospace.com****. Also follow her on* ***LinkedIn****.*

*Nadia Bey is a freelance reporter from North Carolina. Her work and contact information are available at nadiabey.com.*

## Related links

- **FDA Adcomm Backs J&J's Carvykti, BMS's Abecma Early in Multiple Myeloma**
- **BMS's Breyanzi Becomes First CAR-T Therapy for Two Types of Leukemia**
- **FDA Adcomm to Tackle Complexity of CAR-T for Multiple Myeloma**

**Back to news**