FDA warns of rare secondary cancer risk with CAR-T therapies

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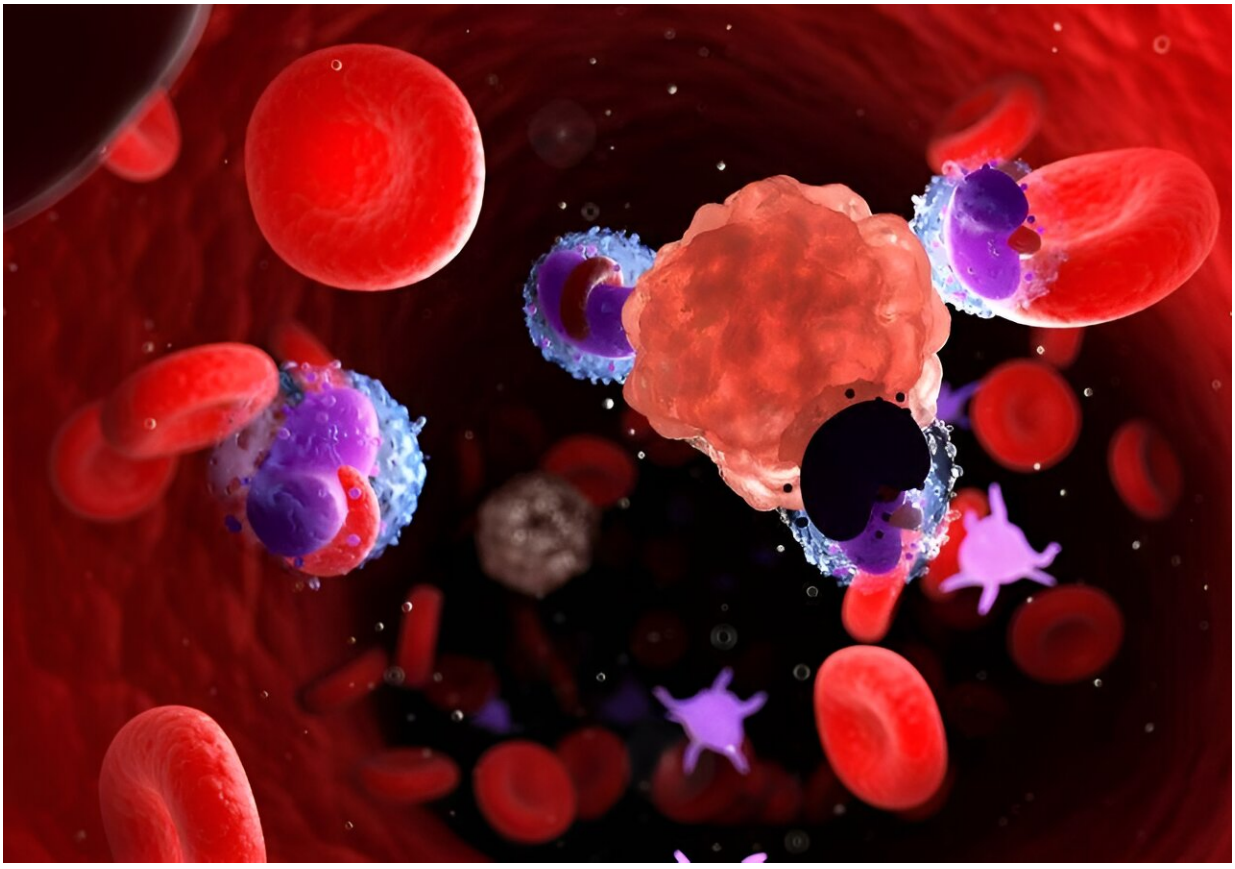

The U.S. Food and Drug Administration has told drugmakers to add a boxed warning to a type of cancer treatment called CAR-T therapy,

saying the treatment itself may sometimes cause a secondary cancer.

Still, FDA spokesperson Carly Kempler told *NBC News* that, despite the new warning, "the overall benefits of these products continue to outweigh their potential risks."

Twenty-five reports of rare blood cancers in patients who had gotten CAR-T therapy prompted the agency to add the boxed warning, Kempler said.

CAR-T therapy uses a patient's own immune cells to fight blood cancers such as leukemia, multiple myeloma and lymphoma. Immune cells are harvested from the patient and then genetically altered in a lab to make them target cancer cells. Once tweaked, the immune cells are infused back into the patient.

It's a powerful therapy: In 2022, doctors who had treated two leukemia patients with CAR-T a decade ago reported that the treatment had essentially cured the patients.

"This has been a game changer when we think about treating lymphoma and other diseases," Dr. Matthew Frigault, clinical director of the Massachusetts General Hospital Cellular Immunotherapy Program, told *NBC News*.

In 2017, the first CAR-T therapy, Novartis' drug Kymriah, was approved by the FDA. Another five therapies have since been approved.

The makers of five of these drugs—Bristol Myers Squibb, for Abecma and Breyanzi; Gilead Sciences' Kite Pharma, for Yescarta; Johnson & Johnson's Carvykti; and Novartis, for Kymriah—must submit proposed label changes in the next 30 days to note that CAR-T therapy can raise the risk of rare blood cancers, the FDA said.

If the drugmakers disagree, they can submit a rebuttal explaining why a change isn't needed, *NBC News* reported.

In a statement, a spokesperson for Novartis said the company has not found "sufficient evidence" to support a link between cancer and its treatment. However, the company will work with the FDA to update its label "appropriately," the spokesman said.

Spokespersons for Johnson & Johnson and Gilead Sciences also told *NBC News* that they would work with the agency to update their labels.

A spokesperson for Bristol Myers Squibb said the company is evaluating "next steps" following the FDA's notice, although it has not seen any cancer cases associated with its treatment.

CAR-T treatments are still relatively new, Frigault noted, so the FDA has required the makers of these therapies to conduct 15-year follow-up studies to measure the potential risk of secondary cancers.

The FDA "is not saying that every single one of the cases they've reported has clearly shown CAR-T has led to this, but more that there may be an association," he said. "This is what the FDA does. They look for a signal."

If CAR-T does cause cancer, the risk is likely very small, Dr. Hemant Murthy, a hematology-oncology physician at the Mayo Clinic in Florida, told *NBC News.*

"I don't really see this affecting too much of practice," Murthy said.

Dr. Saad Usmani, a myeloma physician and cell therapist at Memorial Sloan Kettering, noted that other cancer treatments, such as radiation and chemotherapy, also carry a risk of secondary cancers.

"The [boxed warning] change is expected given the recent reports, albeit very low incidence in such cases," he told *NBC News*.

More information: The National Cancer Institute has more on CAR-T therapy.