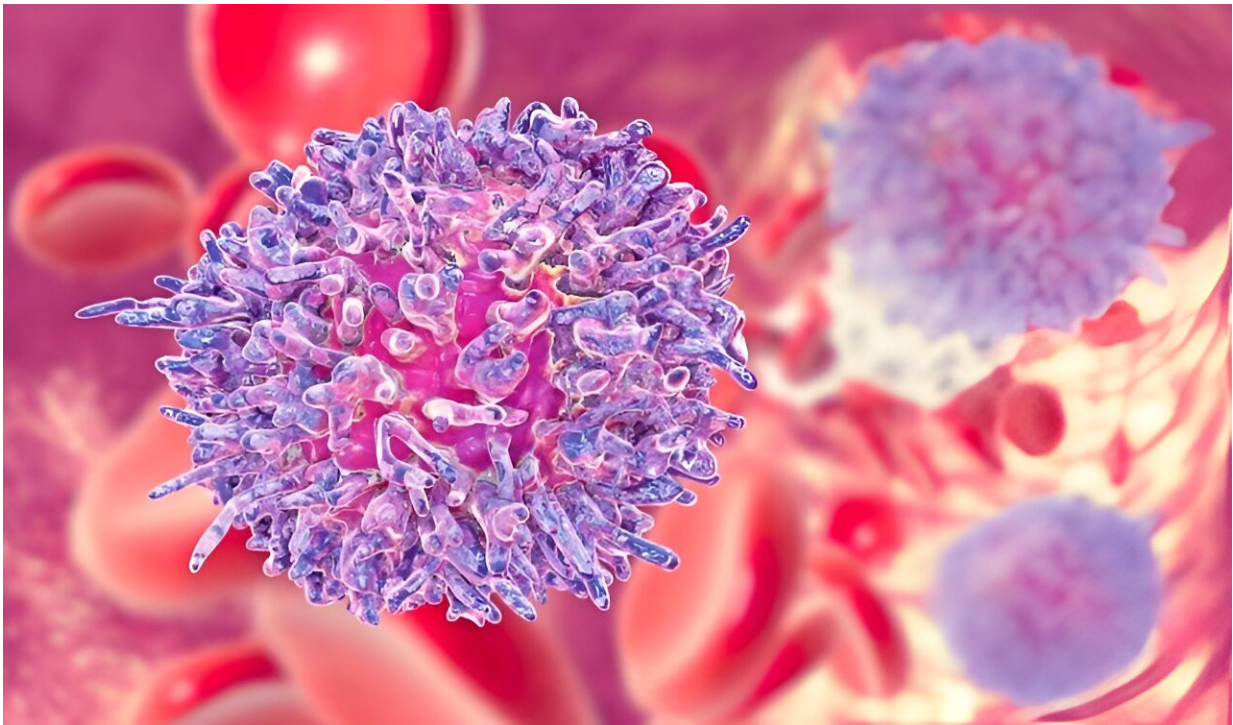


FDA approves first CAR T-cell therapy for adults with leukemia or lymphoma

March 19 2024, by Lori Solomon



The U.S. Food and Drug Administration has approved Bristol Myers Squibb's Breyanzi (lisocabtagene maraleucel [liso-cel]) as the first CD19-directed chimeric antigen receptor (CAR) T-cell therapy for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

The expanded approval for the one-time personalized infusion is for adults who have received at least two prior lines of therapy, including a Bruton tyrosine [kinase inhibitor](#) (BTKi) and a B-cell lymphoma 2 inhibitor (BCL2i). Boxed warnings for Breyanzi include risks for cytokine release syndrome, neurologic toxicities, and secondary hematological malignancies.

The accelerated approval was based on response rate and duration of response in the TRANSCEND CLL 004 study, the first pivotal multicenter trial to evaluate a CAR T-cell therapy in patients with relapsed or refractory CLL or SLL.

The results of the phase 1/2 trial of 89 patients indicated a complete response rate of 20 percent with Breyanzi treatment. For those achieving a complete response, the median duration of response was not yet reached.

The overall response rate was 45 percent, with a median duration of response of 35.3 months. Across patients treated with Breyanzi who achieved a complete response, the minimal residual disease negativity rate was 100 percent in the blood and 92.3 percent in the bone marrow.

"The FDA approval of liso-cel in relapsed or refractory CLL and SLL after treatment with prior BTKi and BCL2i is a remarkable breakthrough, shifting the treatment paradigm from continuous therapy with sequential regimens to overcome [drug resistance](#), to a one-time personalized T-cell based approach that has the potential to offer patients complete and lasting remission," lead investigator Tanya Siddiqi, M.D., from the City of Hope National Medical Center in Duarte, California, said in a statement.

More information: [More Information](#)

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