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More than half of patients alive 2 years after receiving CAR-T therapy for diffuse large B-cell lymphoma in ZUMA-1 trial

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A follow-up analysis of patients enrolled in a Phase I/II multi-center trial for diffuse large B-cell lymphoma (DLBCL) reported 51 percent of patients receiving an anti-CD19 chimeric antigen receptor (CAR T) called axi-cel were still alive two years post-treatment. Axi-cel was approved by the U.S. Food and Drug Administration for treatment of DLBCL in October 2017 and by the European Commission in August 2018.

The study, co-led by Sattva Neelapu, M.D., professor of Lymphoma & Myeloma at The University of Texas MD Anderson Cancer Center, reported its findings in the Dec. 2 online issue of The Lancet Oncology and during a presentation at the 60th American Society of Hematology Annual Meeting & Exposition in San Diego.

"This two-year assessment demonstrates that axi-cel can induce durable remissions in a substantial proportion of patients with an acceptable long-term safety profile," said Neelapu. "There also is evidence of gradual B-cell recovery in most patients with refractory large B-cell lymphoma who otherwise have limited treatment options."

With a median follow-up of 27.1 months for 101 patients enrolled in Phase II, the study found that 83 percent of patients achieved a reduction in cancer activity tied to treatment, known as an objective response; 58 percent had no detectable cancer or a complete response, and 39 percent

reported ongoing responses. Median overall survival was not reached, and no axi-cel related adverse effects were reported after the 12-month period.

The results mirrored findings of a previously reported median follow up of 15.4 months at which time objective response rate was 82 percent, complete response rate was 58 percent, with 42 percent of patients reporting ongoing responses.

In addition, exploratory analyses were performed to assess CAR T-cell persistence and B-cell recovery in patients with ongoing remission, and at 24 months, persisting CAR gene-marked cells were observed in 66 percent of patients with evaluable biomarker samples. Peripheral blood B-cells were measurable in 75 percent of patients.

'Real-world' outcomes support ZUMA-1 findings

A subsequent "real-world" assessment of 274 patients who received axi-cel, post FDA-approval of the therapy revealed similar results to the overall ZUMA-1 study. The real-world retrospective study included 17 centers that contributed data independent from the manufacturer-funded trial.

Findings from the study, led by Loretta Nastoupil, M.D., assistant professor of Lymphoma & Myeloma, were presented Dec. 1 at the ASH Annual Meeting & Exposition. By day 90, the real-world assessment reported 81 percent of patients had an objective response and 57 percent had a complete response.

"Although limited by a relatively short follow up, 90-day responses in the real-world setting are comparable to the best responses observed in the pivotal ZUMA-1 clinical trial," said Nastoupil. "Importantly, safety appears comparable to the ZUMA-1 trial despite nearly half of patients

failing to meet ZUMA-1 eligibility criteria."

Provided by University of Texas M. D. Anderson Cancer Center