

New study highlights CAR T-cell therapy success for lymphoma when used as standard of care

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Chimeric antigen receptor T-cell therapy, or CAR T, was named the 2017 Advance of the Year by the American Society of Clinical Oncology. The FDA approved two CAR T products last year for treatment of adult large B-cell lymphoma based on the exceptional patient outcomes seen in clinical trials. Now, a follow-up study of one of those products shows that it matches clinical trial outcomes when used as a standard of care.

Moffitt Cancer Center partnered with 16 academic cancer centers to analyze real world data of 274 <u>patients</u> treated commercially with Yescarta (axicabtagene ciloleucel), one of two CAR T products that is now standard of care for patients with diffuse large B cell lymphoma (DLBCL) who have not responded to two or more therapies. The researchers then compared those figures with results from the pivotal ZUMA-1 trial, which included 101 patients. The final comparison results, which were presented Saturday, Dec. 1 at the American Society of Hematology Annual Meeting, showed Yescarta induces remissions in DLBCL patients when administered as a standard of care.

"Now that Yescarta is a standard of care for patients with large B cell lymphoma that has progressed after two prior lines of <u>therapy</u>, we wanted to compare the standard of care outcomes, including response rates and onset of side effects, with the results from the clinical trial that led to the therapy's approval," said Michael Jain, M.D., Ph.D., co-first



author of the study and assistant member of Moffitt's Blood and Marrow Transplant and Cellular Immunotherapy. "Our results showed that patient response rates, and the toxicity profile, were consistent with the ZUMA-1 trial results."

The real world data showed that at a median follow-up of four months, 81 percent of patients in the standard of care group responded to the therapy with 58 percent showing no detectable cancer. At the time of Yescarta's FDA approval (Oct. 2017), results from the ZUMA-1 clinical trial showed 72 percent of patients treated responded to therapy including 51 percent who had no detectable cancer remaining at a median follow-up of 7.9 months.

"This study echoes the early results in the ZUMA-1 clinical trial and provides further evidences that CAR T-cell therapy, such as Yescarta, is a feasible option for patients who would otherwise have no viable treatments options," said Frederick Locke, M.D., associate member and vice chair of the Blood and Marrow Transplant and Cellular Immunotherapy Department, and co-leader of the Immunology Program at Moffitt., who served as co-senior author of the study.

Provided by H. Lee Moffitt Cancer Center & Research Institute

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