

# Axicabtagene ciloleucel approved for second-line treatment of large B-cell lymphoma

April 15 2022

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Axicabtagene ciloleucel (axi-cel; Yescarta) was approved for treatment

of large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within a year of first-line chemotherapy, the U.S. Food and Drug Administration announced April 1.

The approval of this chimeric antigen receptor (CAR) T-cell therapy offers an alternative to the standard of care for LBCL, a multistep process that starts with chemoimmunotherapy and then involves high-dose chemotherapy and a [stem cell transplant](#) for patients who respond to and can tolerate further treatment. CAR T-cell therapies are made from a patient's white blood cells (T cells), which are removed and sent to a specialized manufacturing facility to be engineered to treat the patient's cancer and are then infused back into the patient. Physicians and patients can begin accessing Yescarta T-cell therapy through authorized treatment centers in the United States.

The FDA based its approval on data from ZUMA-7, a randomized, open-label, multicenter trial of 359 patients with primary refractory LBCL or relapse within one year after completion of first-line therapy.

Researchers randomly assigned patients to a single infusion of axi-cel following fludarabine and cyclophosphamide lymphodepleting chemotherapy or to second-line chemotherapy consisting of two or three cycles of chemoimmunotherapy followed by high-dose therapy and autologous hematopoietic stem cell transplantation in patients who attained complete or partial remission.

Patients in the axi-cel arm achieved significantly longer event-free survival (hazard ratio, 0.40), with an estimated 18-month event-free survival rate of 41.5 percent compared with 17.0 percent in the standard therapy arm. Estimated median event-free survival was 8.3 and 2.0 months in the axi-cel and standard therapy arms, respectively.

The prescribing information for axi-cel includes a boxed warning for

[cytokine release syndrome](#) and neurologic toxicities. The most commonly reported [adverse reactions](#) have included cytokine release syndrome, fever, hypotension, encephalopathy, fatigue, tachycardia, headache, nausea, febrile neutropenia, diarrhea, musculoskeletal pain, infections, chills, and decreased appetite.

Approval was granted to Kite Pharma Inc.

**More information:** [FDA Approval](#)

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