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

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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