

# FDA Approves Axicabtagene Ciloleucel for Large B-Cell Lymphoma

Yescarta is the first chimeric antigen receptor T cell (CAR-T) immunotherapy approved for adults.

October 25, 2017 By [Food and Drug Administration \(FDA\)](#)

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On October 18, 2017, the Food and Drug Administration granted regular approval to axicabtagene ciloleucel (YESCARTA, Kite Pharma, Inc.) for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Axicabtagene ciloleucel is a chimeric antigen receptor (CAR) T cell immunotherapy. It consists of autologous T cells that are genetically modified to produce a CAR protein, allowing the T cells to identify and eliminate CD19-expressing normal and malignant cells.

Approval was based on a single-arm multicenter trial of 108 adult patients with aggressive B-cell non-Hodgkin lymphoma. Eligible patients had refractory disease to the most recent therapy or relapse within one year after autologous hematopoietic stem cell transplantation. Patients received a single infusion of axicabtagene ciloleucel following completion of lymphodepleting chemotherapy.

Of the 101 patients evaluated for efficacy, the objective response rate (ORR) as assessed by independent central review was 72%, with a complete remission (CR) rate of 51% (95% CI: 41, 62). The duration of response (DOR) was longer in patients with a best overall response of CR, as compared to a best overall response of partial remission (PR). Among patients achieving CR, the estimated median DOR was not reached (95% CI: 8.1 months, not estimable [NE]) after a median follow-up of 7.9-months. The estimated median DOR among patients in PR was 2.1 months (95% CI: 1.3, 5.3).

The most common grade 3 or higher adverse reactions (incidence of 10% or greater) include febrile neutropenia, fever, cytokine release syndrome (CRS), encephalopathy, infections, hypotension, and hypoxia. Serious adverse reactions occurred in 52% of patients and included CRS, neurologic toxicity, prolonged cytopenias (including neutropenia, thrombocytopenia, and anemia), and serious infections. Fatal cases of CRS and neurologic toxicity occurred. FDA approved axicabtagene ciloleucel with a Risk Evaluation and Mitigation Strategy.

The recommended dose of axicabtagene ciloleucel is a single intravenous infusion with a target of

$2 \times 10^6$  CAR-positive viable T cells per kg body weight (maximum  $2 \times 10^8$ ), preceded by fludarabine and cyclophosphamide lymphodepleting chemotherapy. Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

Full prescribing information is available

at: <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm581222.htm>.

FDA granted orphan drug designation and priority review to axicabtagene ciloleucel for this indication. Approval was granted approximately 6 weeks prior to the due date. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available

at: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at <http://www.fda.gov/medwatch/report.htm>, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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