

# FDA Approves Yescarta for Second-Line Treatment of Large B-cell Lymphoma

The personalized CAR-T therapy prolonged cancer remission compared with standard therapy.

April 7, 2022 By [Food and Drug Administration \(FDA\)](#)

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On April 1, 2022, the Food and Drug Administration approved axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

Approval was based on [ZUMA-7](#), a randomized, open-label, multicenter trial in adult patients with primary refractory LBCL or relapse within 12 months following completion of first-line therapy. Patients had not yet received treatment for relapsed or refractory lymphoma and were potential candidates for autologous hematopoietic stem cell transplantation (HSCT).

A total of 359 patients were randomized 1:1 to receive a single infusion of axicabtagene ciloleucel following fludarabine and cyclophosphamide lymphodepleting chemotherapy or to receive second-line standard therapy, consisting of 2 or 3 cycles of chemoimmunotherapy followed by high-dose therapy and autologous HSCT in patients who attained complete remission or partial remission.

The primary efficacy measure was event-free survival (EFS) determined by an independent review committee (IRC). EFS was significantly longer in the axicabtagene ciloleucel arm with a hazard ratio of 0.40 (95% CI: 0.31, 0.51; stratified p-value <0.0001). The estimated 18-month EFS rate was 41.5% (95% CI: 34.2, 48.6) in the axicabtagene ciloleucel arm and 17.0% (95% CI: 11.8, 23.0) in the standard therapy arm. The estimated median EFS was 8.3 months (95% CI: 4.5, 15.8) and 2.0 months (95% CI: 1.6, 2.8), respectively.

Of patients randomized to receive standard therapy, 35% received on-protocol autologous HSCT; lack of response to chemotherapy was the most common reason for not receiving HSCT. The IRC-assessed best objective response rate was statistically significantly higher in the axicabtagene ciloleucel arm compared to the standard therapy arm: 83% (95% CI: 77, 88) vs. 50% (95% CI: 43, 58), respectively.

The prescribing information for axicabtagene ciloleucel has a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities. In studies of axicabtagene ciloleucel in patients with non-Hodgkin lymphoma, CRS occurred in 90% (Grade  $\geq$ 3, 9%) and neurologic toxicities occurred in 78% (Grade  $\geq$ 3, 25%).

The most common non-laboratory adverse reactions (incidence  $\geq 30\%$ ) are CRS, fever, hypotension, encephalopathy, fatigue, tachycardia, headache, nausea, febrile neutropenia, diarrhea, musculoskeletal pain, infections with pathogen unspecified, chills, and decreased appetite.

The recommended axicabtagene ciloleucel dose is  $2 \times 10^6$  chimeric antigen receptor (CAR)-positive viable T cells per kg of body weight, with a maximum of  $2 \times 10^8$  CAR-positive viable T cells.

[View full prescribing information for Yescarta.](#)

This review used the [Assessment Aid](#), a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review, breakthrough therapy designation, and orphan drug designation. A description of FDA expedited programs is in the [Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics](#).

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](#) or by calling 1-800-FDA-1088.

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