FDA Approves Yescarta for Follicular Lymphoma

The CAR-T therapy led to complete remission in 60% of people with relapsed or refractory follicular lymphoma.

March 9, 2021 By Food and Drug Administration (FDA)

FDA grants accelerated approval to axicabtagene ciloleucel for relapsed or refractory follicular lymphoma

On March 5, 2021, the Food and Drug Administration granted accelerated approval to axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Approval in FL was based on a single-arm, open-label, multicenter trial (ZUMA-5; NCT03105336) that evaluated axicabtagene ciloleucel, a CD19-directed chimeric antigen receptor (CAR) T cell therapy, in adult patients with relapsed or refractory FL after two or more lines of systemic therapy, including the combination of an anti-CD20 monoclonal antibody and an alkylating agent. Following lymphodepleting chemotherapy, axicabtagene ciloleucel was administered as a single intravenous infusion.

The main efficacy measures were objective response rate (ORR) and duration of response (DOR) as determined by an independent review committee. Among 81 patients in the primary efficacy analysis, the ORR was 91% (95% CI: 83, 96) with a complete remission (CR) rate of 60% and a median time-to-response of 1 month. The median DOR was not reached, and the 1-year rate of continued remission was 76.2% (95% CI: 63.9, 84.7). For all leukapheresed patients in this trial (n=123), the ORR was 89% (95% CI: 83, 94) with a CR rate of 62%.

The prescribing information for axicabtagene ciloleucel has a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities. In studies of axicabtagene ciloleucel among all patients with non-Hodgkin’s lymphoma (NHL), CRS occurred in 88% (Grade ≥3, 10%) and neurologic toxicities occurred in 81% (Grade ≥3, 26%). The most common non-laboratory adverse reactions (incidence ≥20%) in patients with NHL are CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, febrile neutropenia, nausea, infections with pathogen unspecified, decreased appetite, chills, diarrhea, tremor, musculoskeletal pain, cough, hypoxia, constipation, vomiting, arrhythmias, and dizziness.

Click here for full prescribing information for Yescarta.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

This application was granted priority review, breakthrough 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.

This announcement was originally published on the Food and Drug Administration website on March 5, 2021.

© 2026 Smart + Strong All Rights Reserved.