FDA Approves Tecartus CAR-T Therapy for Acute Lymphoblastic Leukemia

Half of patients treated with the customized T cells achieved complete remission.

November 25, 2021 By Food and Drug Administration (FDA)

FDA approves brexucabtagene autoleucel for relapsed or refractory B-cell precursor acute lymphoblastic leukemia

On October 1, 2021, the Food and Drug Administration approved brexucabtagene autoleucel (Tecartus, Kite Pharma, Inc.) for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Efficacy was evaluated in ZUMA-3 (NCT02614066), a single-arm multicenter trial that evaluated brexucabtagene autoleucel, a CD19-directed chimeric antigen receptor (CAR) T-cell therapy, in adults with relapsed or refractory B-cell precursor ALL. Patients received a single infusion of brexucabtagene autoleucel following completion of lymphodepleting chemotherapy.

The efficacy outcome measures used to support approval were complete response (CR) achieved within 3 months from infusion and duration of CR. Of the 54 patients evaluable for efficacy, 28 (52%; 95% CI: 38, 66) achieved CR within 3 months. With a median follow-up for responders of 7.1 months, the median duration of CR was not reached; the duration of CR was estimated to exceed 12 months for more than half the patients.

The prescribing information for brexucabtagene autoleucel has a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities. CRS occurred in 92% (Grade ≥3, 26%) and neurologic toxicities occurred in 87% (Grade ≥3, 35%). The most common non-laboratory adverse reactions (incidence ≥ 20%) included fever, CRS, hypotension, encephalopathy, tachycardias, nausea, chills, headache, fatigue, febrile neutropenia, diarrhea, musculoskeletal pain, hypoxia, rash, edema, tremor, infection with pathogen unspecified, constipation, decreased appetite, and vomiting.

The recommended brexucabtagene autoleucel dose is a single intravenous infusion of 1 x 106 CAR-positive viable T cells per kg body weight (maximum 1 x 108 CAR-positive viable T cells), preceded by fludarabine and cyclophosphamide for lymphodepleting chemotherapy.

See full prescribing information for Tecartus.

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 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 by the Food and Drug Administration on October 1, 2021.
