FDA Approves Epkinly for Advanced B-Cell Lymphoma

The overall response rate was 61% for patients treated with the bispecific T-cell engager.

May 25, 2023 By Food and Drug Administration (FDA)

FDA grants accelerated approval to epcoritamab-bysp for relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma

On May 19, 2023, the Food and Drug Administration granted accelerated approval to epcoritamab-bysp (Epkinly, Genmab US, Inc.) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

View full prescribing information for Epkinly.

Epcoritamab-bysp, a , was evaluated in EPCORE NHL-1 (NCT03625037), an open-label, multi-cohort, multicenter, single-arm trial in patients with relapsed or refractory B-cell lymphoma. The efficacy population consisted of 148 patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy, including at least one anti-CD20 monoclonal antibody-containing therapy.

The main efficacy outcome measure was overall response rate (ORR) determined by Lugano 2014 criteria, as assessed by an Independent Review Committee. The ORR was 61% (95% CI: 53, 69) with 38% of patients achieving complete responses. With a median follow-up of 9.8 months among responders, the estimated median duration of response (DOR) was 15.6 months (95%CI: 9.7, not reached).

The prescribing information has a Boxed Warning for serious or life-threatening cytokine release syndrome (CRS) and life-threatening or fatal immune effector cell-associated neurotoxicity syndrome (ICANS). Warnings and precautions include infections and cytopenias. Among the 157 patients with relapsed or refractory large B-cell lymphoma who received epcoritamab-bysp at the recommended dose, CRS occurred in 51% of patients, ICANS in 6%, and serious infections in 15%. For CRS, Grade 1 occurred in 37% of patients, Grade 2 in 17%, and Grade 3 in 2.5%. For ICANS, Grade 1 occurred in 4.5%, Grade 2 in 1.3%, and Grade 5 in 0.6%.

Epcoritamab-bysp should only be administered by a qualified healthcare professional with

appropriate medical support to manage severe reactions such as CRS and ICANS. Because of the risk of CRS and ICANS, patients should be hospitalized for 24 hours after the Cycle 1 Day 15 dosage of 48 mg.

The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

The recommended regimen consists of epcoritamab-bysp administered subcutaneously in 28-day cycles until disease progression or unacceptable toxicity. The recommended dose is step-up dosing in Cycle 1 (0.16 mg on Day 1, 0.8 mg on Day 8, and 48 mg on Day 15 and Day 22) followed by fixed dosing of 48 mg weekly dosing during Cycles 2 through 3, every other week during Cycle 4 through 9, and then every four weeks on Day 1 of subsequent cycles.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review. FDA expedited programs are described 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 published by the Food and Drug Administration on May 19, 2023.
