FDA Grants Accelerated Approval to Epkinly for Relapsed or Refractory Follicular Lymphoma

The FDA has granted accelerated approval to epcoritamab-bysp (Epkinly, Genmab U.S.), a bispecific CD20-directed CD3 T-cell engager, for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Efficacy and safety were evaluated in EPCORE NHL-1 (Study GCT3013-01; ClinicalTrials.gov. Identifier: NCT03625037), an open-label, multi-cohort, multicenter single-arm trial that included 127 patients with relapsed or refractory FL after at least two lines of systemic therapy. The primary efficacy and safety were based on 127 patients who received a two-step-up dosing regimen. A separate dose-optimization cohort of 86 patients evaluated the recommended three-step-up dosage schedule for cytokine release syndrome (CRS) mitigation.

The main efficacy outcome measures were overall response rate (ORR) and duration of response (DOR), determined by an independent review committee using the Lugano 2014 criteria. In the 127 patients in the primary efficacy population, the ORR was 82% (95% CI, 74.1%-88.2%) with 60% achieving complete responses. With an estimated median follow-up of 14.8 months among responders, the estimated median DOR was not reached (NR) (95% CI, 13.7 months to NR). The 12-month Kaplan-Meier estimate for DOR was 68.4% (95% CI, 57.6%-77.0%). Efficacy was similar in the 86 patients who received the three-step-up dosage schedule.

The prescribing information includes a boxed warning for serious or fatal CRS and immune effector cell–associated neurotoxicity (ICANS). Warnings and precautions include serious infections and cytopenias. ICANS occurred in 6.0%, and serious infections in 40%. Among 86 patients with relapsed or refractory FL who received the recommended three-step-up dosage regimen, CRS occurred in 49%; all events were grades 1 (45%) and 2 (9%).

The most common adverse reactions (≥20%) were injection site reactions, CRS, COVID-19 infection, fatigue, upper respiratory tract infection, musculoskeletal pain, rash, diarrhea, pyrexia, cough and headache. The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count and decreased hemoglobin.

News Source:

https://www.pharmacypracticenews.com/FDA-News/Oncology/Article/06-24/FDA-Grants-Accelerated-Approval-to-Epkinly-for-Relapsed-or-Refractory-Follicular-Lymphoma/74162