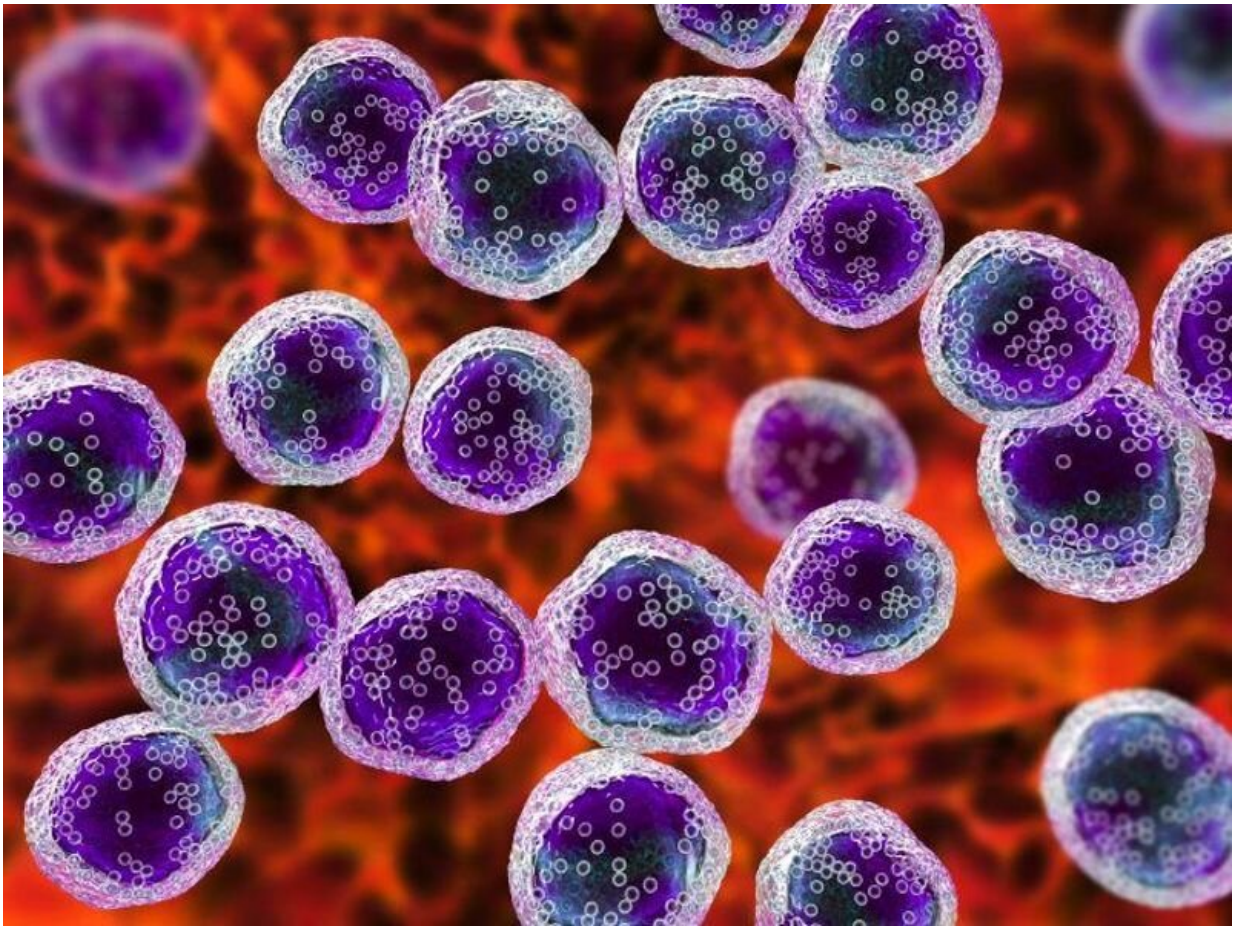
Epkinly granted accelerated FDA approval for lymphoma treatment

May 23 2023, by Lori Solomon



The U.S. Food and Drug Administration has granted accelerated

approval for Genmab's Epkinly (epcoritamab-bysp) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma.

The recommended regimen consists of Epkinly administered subcutaneously in 28-day cycles until disease progression or unacceptable toxicity. Step-up dosing is recommended with 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.

Approval was based on trial data from 148 patients with relapsed or refractory DLBCL. The overall response rate, assessed by an independent review committee, was 61%, with 38% of patients achieving complete responses. During a median follow-up of 9.8 months among responders, the estimated median duration of response was 15.6 months.

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. Infections and cytopenias are included as warnings and precautions. The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea, while the most common grade 3 to 4 laboratory abnormalities (≥10%) included decreases in lymphocyte count, neutrophil count, white blood cell count, hemoglobin, and platelets.

More information: More Information