Epkinly® (epcoritamab-bysp) – New indication

- On June 26, 2024, AbbVie and Genmab announced the FDA approval of Epkinly (epcoritamab-bysp), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
    - This indication is approved under accelerated approval based on response rate and durability of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Epkinly is also approved for the treatment of adult patients with 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.
- The approval of Epkinly for the new indication was based on EPCORE NHL-1, an open-label, multi-cohort, single-arm study that included 127 patients with relapsed or refractory FL after at least two lines of systemic therapy. Patients received Epkinly until disease progression or unacceptable toxicity. Efficacy was established based on overall response rate (ORR) and DOR.
    - The ORR was 82% (95% CI: 74.1, 88.2).
    - The median DOR was not reached (95% CI: 13.7 months, not reached).
- Epkinly carries a boxed warning for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).
- The most common adverse reactions (≥ 20%) with Epkinly use for FL were injection site reactions, CRS, COVID-19, 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.
- Epkinly is administered subcutaneously according to a step-up dosage schedule for patients with FL to reduce the incidence and severity of CRS (see table below). Epkinly should be administered in 28-day cycles until disease progression or unacceptable toxicity.

Cycle of treatment	Day of treatment	Dose of Epkinly	
Cycle 1	1	Step-up dose 1	0.16 mg
	8	Step-up dose 2	0.8 mg
	15	Step-up dose 3	3 mg
	22	First full dose	48 mg
Cycles 2 and 3	1, 8, 15, and 22	48 mg	
Cycles 4 to 9	1 and 15	48 mg	
Cycle 10 and beyond	1	48 mg	

- Epkinly should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and ICANS.
- Refer to the Epkinly drug label for dosing for DLBCL.