Optum Rx®

## Epkinly™ (epcoritamab-bysp) – New drug approval

- On May 19, 2023, the FDA announced the approval of AbbVie's Epkinly (epcoritamab-bysp), 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.
    - This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- DLBCLs are the most common type of non-Hodgkin lymphoma cancer and are marked by rapidly growing tumors in the lymph nodes, spleen, liver, bone marrow, or other tissues and organs. High-grade B-cell lymphoma is an aggressive form of B-cell lymphoma.
- Epkinly is a bispecific antibody designed to direct cytotoxic T cells selectively to elicit an immune response towards target cell types. It is designed to simultaneously bind to CD3 on T cells and CD20 on B-cells and induces T cell mediated killing of CD20+ cells.
- The efficacy of Epkinly was established in EPCORE NHL-1, an open-label, multi-cohort, single-arm study in 157 patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy. Patients received Epkinly until disease progression or unacceptable toxicity. Efficacy was established based on overall response rate (ORR) and duration of response (DOR).
    - The ORR was 61% (95% CI: 52.5, 68.7).
    - The median DOR was 15.6 months (95% CI: 9.7, not reached).
- Epkinly carries a boxed warning for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).
- Additional warnings and precautions for Epkinly include infections, cytopenias, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Epkinly use were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥ 10%) with Epkinly use were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.
- The recommended dosage schedule for Epkinly is provided in the table below. Epkinly should be administered subcutaneously 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 | First full dose | 48 mg |
| | 22 | 48 mg | |
| Cycles 2 and 3 | 1, 8, 15, and 22 | 48 mg | |
| Cycles 4 to 9 | 1 and 15 | 48 mg | |

Continued . . .

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| 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.

- AbbVie's launch plans for Epkinly are pending. Epkinly will be available as a 4 mg/0.8 mL and 48 mg/0.8 mL single-dose vial.