Breyanzi® (lisocabtagene maraleucel) – New indication

- On May 15, 2024, Bristol Myers Squibb announced the FDA approval of Breyanzi (lisocabtagene maraleucel), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy.
    - Breyanzi is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- Breyanzi is also approved for the treatment of large B-cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma.
- The approval of Breyanzi for the new indication was based on TRANSCEND-FL, an open-label, single-arm study in adult patients with relapsed or refractory FL after two or more lines of systemic therapy. A single dose of Breyanzi was administered 2 to 7 days following completion of lymphodepleting chemotherapy. The primary efficacy analysis included 94 patients. Efficacy was based on overall response rate (ORR).
    - The ORR rate was 95.7% (95% CI: 89.5, 98.8).
    - The median duration of response was not reached (95% CI: 18.04, not reached).
- Breyanzi carries a boxed warning for cytokine release syndrome (CRS), neurologic toxicities, and secondary hematological malignancies.
- The most common adverse reaction (≥ 30%) with Breyanzi use for FL was CRS. The most common grade 3-4 laboratory abnormalities included decreased lymphocyte count, decreased neutrophil count, and decreased white blood cell.
- The recommended single dose of Breyanzi for FL is 90 to 110 × 10^6 CAR-positive viable T cells.
    - Refer to the Breyanzi drug label for complete dosing and administration recommendations for FL and its other indications.