Breyanzi® (lisocabtagene maraleucel) – New indication

- On May 30, 2024, Bristol Myers Squibb announced the FDA approval of Breyanzi (lisocabtagene maraleucel), for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

- Breyanzi is also approved for the treatment of large B-cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, and follicular lymphoma.

- Breyanzi is a CD19-directed chimeric antigen receptor (CAR) T cell therapy.

- The approval of Breyanzi for the new indication was based on TRANSCEND-MCL, an open-label, single-arm study in adult patients with relapsed or refractory MCL who had received at least two prior lines of therapy including a BTK inhibitor, an alkylating agent, and an anti-CD20 agent. Efficacy was based on overall response rate (ORR).

    — The ORR was 85.3% (95% CI: 74.6, 92.7) in Breyanzi-treated patients.
    — The median duration of response was 13.3 months (95% CI: 6.0, 23.3).

- Breyanzi carries a boxed warning for cytokine release syndrome (CRS), neurologic toxicities, and secondary hematological malignancies.

    — Breyanzi is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi REMS.

- The most common adverse reactions (≥ 30%) with Breyanzi use were CRS, fatigue, musculoskeletal pain, and encephalopathy. The most common grade 3-4 laboratory abnormalities include decreased neutrophil count, decreased white blood cell, and decreased platelet count.

- The recommended single dose of Breyanzi for MCL is 90 to 110 × 10^6 CAR-positive viable T cells.

    — Refer to the Breyanzi drug label for complete dosing and administration recommendations for MCL and its other indications.