

## Breyanzi® (lisocabtagene maraleucel) - New indication

- On May 30, 2024, <u>Bristol Myers Squibb announced</u> the FDA approval of <u>Breyanzi (lisocabtagene maraleucel)</u>, 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<sup>6</sup> CAR-positive viable T cells.
  - Refer to the Breyanzi drug label for complete dosing and administration recommendations for MCL and its other indications.



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