Breyanzi® (lisocabtagene maraleucel) – Expanded indications

- On June 24, 2022, Bristol Myers Squibb announced the FDA approval of Breyanzi (lisocabtagene maraleucel), for the treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have:
    - Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
    - Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age.

- Breyanzi is also approved for the indication in patients with relapsed or refractory disease after two or more lines of systemic therapy.

- The approval of Breyanzi for the expanded indication was based on TRANSFORM, a randomized, open-label study in 184 adult patients with relapsed or refractory LBCL after first-line chemoimmunotherapy. Patients were randomized to receive a single infusion of Breyanzi or to receive standard therapy consisting of 3 cycles of chemoimmunotherapy followed by high-dose therapy and autologous HSCT in patients who attained complete response (CR) or partial response. The primary efficacy measure was event-free survival (EFS) and other efficacy measures included progression-free survival (PFS).
    - Median EFS was 10.1 months in the Breyanzi arm vs. 2.3 months in the standard therapy arm (hazard ratio [HR] 0.34, 95% CI: 0.22, 0.52; $p < 0.0001$).
    - Median PFS was 14.8 months in the Breyanzi arm vs. 5.7 months in the standard therapy arm (HR 0.41, 95% CI: 0.25, 0.66; $p = 0.0001$).

- In addition, Breyanzi was evaluated in PILOT, a single-arm, open-label study in transplant-ineligible patients with relapsed or refractory LBCL after one line of chemoimmunotherapy. A total of 61 patients received Breyanzi. Efficacy was based on CR rate and duration of response (DOR).
    - In the 61 patients, the overall response rate was 80% (95% CI: 68, 89). The CR rate was 54% (95% CI: 41, 67).
    - The median DOR was 11.2 months (95% CI: 5.1, not reached).

- Breyanzi carries a boxed warning for cytokine release syndrome and neurologic toxicities.
    - Breyanzi is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi REMS.

- Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy. Refer to the Breyanzi drug label for complete dosing and administration recommendations.