Breyanzi® (lisocabtagene maraleucel) – New indication

- On March 14, 2024, Bristol Myers Squibb announced the FDA approval of Breyanzi (lisocabtagene maraleucel), for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
    - This indication 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, a CD19-directed genetically modified autologous T cell immunotherapy, is also approved for large B-cell lymphoma.
- The approval of Breyanzi for the new indication was based on open-label, single-arm study in adult patients with relapsed/refractory CLL or SLL who had received at least 2 prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitor. Efficacy was based on overall response rate (ORR).
    - Of the 65 efficacy-evaluable patients, the ORR was 45% (95% CI: 32.3, 57.5).
    - The median duration of response was 35.3 months (95% CI: 12.4, not reached).
- Breyanzi carries a boxed warning for cytokine release syndrome (CRS), neurologic toxicities, and secondary hematological malignancies.
- The most common nonlaboratory adverse reactions (≥ 30%) with Breyanzi use for CLL/SLL were CRS, encephalopathy, fatigue, musculoskeletal pain, nausea, and diarrhea. The most common grade 3-4 laboratory abnormalities (≥ 30%) include decreased neutrophil count, decreased white blood cell, decreased hemoglobin, decreased platelet count, and decreased lymphocyte count.
- The recommended dose of Breyanzi for CLL/SLL is 90 to 110 × 10^6 CAR-positive viable T cells. Refer to the Breyanzi drug label for complete dosing and administration recommendations.