Breyanzi® (lisocabtagene maraleucel) – New orphan drug approval

- On February 5, 2021, the FDA announced the approval of Bristol-Myers Squibb Breyanzi (lisocabtagene maraleucel), for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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.
    - Breyanzi is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.
- DLBCL is the most common type of non-Hodgkin lymphoma in adults. Approximately 77,000 new cases of non-Hodgkin lymphoma are diagnosed in the U.S. each year and DLBCL represents approximately one in three newly diagnosed cases.
- Breyanzi is the third chimeric antigen receptor (CAR) T cell therapy approved by the FDA for certain types of non-Hodgkin lymphoma, including DLBCL.
    - Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy. Each dose of Breyanzi is a customized treatment created using a patient's own T-cells to help fight the lymphoma. The patient's T-cells are collected and genetically modified to include a new gene that facilitates targeting and killing of the lymphoma cells. Once the cells are modified, they are infused back into the patient.
- The efficacy of Breyanzi was established in an open-label, single-arm study in adult patients with relapsed or refractory large B-cell non-Hodgkin lymphoma after at least 2 lines of therapy. Breyanzi was administered 2 to 7 days following completion of lymphodepleting chemotherapy. There were 192 patients included in the main efficacy population. Efficacy was based on complete response (CR) rate and duration of response (DOR).
    - The overall response rate was 73% (95% CI: 67, 80). CR was achieved in 54% (95% CI: 47, 61) of patients.
    - Median DOR was 16.7 months (95% CI: 5.3, not reached).
- Breyanzi carries a boxed warning for cytokine release syndrome (CRS) and neurologic toxicities.
- Breyanzi is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Breyanzi REMS.
    - The FDA is requiring, among other things, that healthcare facilities that dispense Breyanzi be specially certified. As part of that certification, staff involved in the prescribing, dispensing or administering of Breyanzi are required to be trained to recognize and manage the risks of CRS and neurologic toxicities.
    - The REMS program specifies that patients be informed of the signs and symptoms of CRS and neurological toxicities following infusion – and of the importance of promptly returning to the treatment site if they develop fever or other adverse reactions after receiving treatment with Breyanzi.
- Additional warnings and precautions for Breyanzi include hypersensitivity reactions, serious infections, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, and effects on ability to drive and use machines.

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- The most common nonlaboratory adverse reactions (≥ 20%) with Breyanzi use were fatigue, CRS, musculoskeletal pain, nausea, headache, encephalopathy, infections (pathogen unspecified), decreased appetite, diarrhea, hypotension, tachycardia, dizziness, cough, constipation, abdominal pain, vomiting, and edema.
- The expected list price for Breyanzi is $410,000.
- Refer to the Breyanzi drug label for dosing and administration recommendations.
- Bristol-Myers Squibb's launch plans for Breyanzi are pending.

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