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BMS CAR-T Therapy Wins FDA Approval for Expanded Use in Follicular Lymphoma

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Pictured: Bristol Myers Squibb office in California/iStock, ***hapabapa***

The FDA on Wednesday **approved the label expansion** of **Bristol Myers Squibb**'s CAR-T cell therapy Breyanzi (lisocabtagene maraleucel) for the treatment of patients with relapsed or refractory follicular lymphoma.

Wednesday's approval, which expands the use of Breyanzi in patients who had undergone at least two prior lines of systemic therapy, was granted under the FDA's accelerated pathway based on response data. To keep the approval, BMS will need to confirm Breyanzi's clinical

benefit in this indication through a Phase III confirmatory study.

Bryan Campbell, head of commercial, cell therapy at BMS, in a statement called Breyanzi a "cornerstone" of the pharma's cell therapy portfolio, adding that its expansion into relapsed or refractory follicular lymphoma (FL) gives patients a treatment option "with potential for lasting remission in a one-time infusion."

Designed to be administered intravenously, **Breyanzi** is a CD19-directed CAR-T cell therapy that works by targeting B cells. Once bound to the CD19 surface protein, Breyanzi can proliferate and trigger the secretion of proinflammatory cytokines and induce cell death in cancer cells.

Breyanzi was **first approved in February 2021** for the treatment of relapsed or refractory large B-cell lymphoma. In March 2024, the CAR-T therapy picked up **an approval** for small lymphocytic leukemia and chronic lymphocytic leukemia.

Wednesday's label expansion was backed by data from the Phase II **TRANSCEND FL** study, a single-arm, open-label trial that enrolled more than 210 patients with relapsed or refractory FL or marginal zone lymphoma. Results showed that treatment with Breyanzi resulted

in a 95.7% overall response rate, with a complete response rate of 73.4%.

Response to treatment was rapid, with a median onset of one month. Median duration of response was not yet reached at the time of the analysis and 80.9% of patients still showed treatment response at 12 months.

The FDA has another **upcoming decision date** for Breyanzi, on May 31, 2024, for refractory mantle cell lymphoma.

Like all commercially available CAR-T therapies, Breyanzi carries a boxed warning for the risk of secondary hematological malignancies. The FDA in November 2023 **revealed** that it detected and was looking into cases of secondary cancers in patients treated with CAR-T therapies. In January 2024, the regulator **published more details** regarding these adverse events, noting that it had found the CAR transgene in three cases of these secondary cancers.

Breyanzi's boxed warning also warns against cytokine release syndrome and neurologic toxicities.

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