FDA Approves New CAR-T Therapy for Large B-Cell Lymphoma

Half of patients treated with Breyanzi experienced complete remission, and a majority of these responses were durable.

February 8, 2021 By Liz Highleyman

On February 5, the Food and Drug Administration (FDA) approved Breyanzi (lisocabtagene maraleucel, or liso-cel), a new CAR-T therapy for the treatment of adults with relapsed or refractory (nonresponsive) large B-cell lymphoma—the most common type of non-Hodgkin lymphoma—who have been treated with at least two prior lines of therapy.

Breyanzi (formerly known as JCAR017), initially developed by Juno Therapeutics and now produced by Bristol-Myers Squibb, is a "living drug" that reprograms a patient's own T cells to fight cancer. Chimeric antigen receptor T-cell therapy—better known as CAR-T—involves removing a sample of a patient's white blood cells, genetically modifying the T cells to recognize and attack that person's cancer, manufacturing a large number of the modified cells in a laboratory and infusing them back into the body.

"Today's approval represents another milestone in the rapidly progressing field of gene therapy by providing an additional treatment option for adults with certain types of cancer affecting the blood, bone marrow and lymph nodes," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a press release. "Gene and cell therapies have evolved from promising concepts to practical cancer treatment regimens."

Breyanzi targets the CD19 protein on B cells that grow out of control in many types of lymphoma and leukemia. It is designed to have a balanced composition of CD4 "helper" and CD8 "killer" T cells. The approved CAR-T therapies Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel) also target CD19.

Non-Hodgkin lymphoma affects antibody-producing B cells. The Breyanzi indication includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma and Grade 3B follicular lymphoma. About three quarters of people with DLBCL do not respond to or relapse after a second or subsequent line of treatment; for this group, treatment options are limited, and median life expectancy is around six months.

"People battling relapsed or refractory large B-cell lymphoma continue to face a challenging treatment journey, both physically and emotionally," Lymphoma Research Foundation CEO Meghan Gutierrez said in a Bristol-Myers Squibb press release. "Breyanzi is an innovative treatment that offers a new option for patients and another reason for this community to maintain hope for the future."

Approval of Breyanzi is supported by findings from the TRANSCEND NHL 001 study (ClinicalTrials.gov NCT02631044), a multicenter open-label trial that included people with previously treated relapsed or refractory large B-cell lymphoma. They received a single infusion of modified T cells after undergoing strong chemotherapy to kill off some of their own immune cells to make room for the new ones.

Preliminary findings were presented at the 2018 Clinical Immuno-Oncology Symposium. Follow-up results showed that among 192 evaluable patients, the overall response rate was 73%, including 54% with complete remission. The median time to the first response was one month. Among the 104 people who achieved a complete response, 62% had remission lasting at least nine months. The estimated median duration of response was 16.7 months for complete responders, falling to only 1.4 months for partial responders.

Just under half of patients (46%) treated with Breyanzi in this study experienced serious adverse reactions. Introducing engineered T cells can trigger a strong immune reaction known as cytokine release syndrome (CRS), which can lead to fever and chills, falling blood pressure and organ failure. In this study, 46% of participants developed CRS, including 4% with severe cases and one death. About a third experienced neurologic toxicity, with symptoms such as encephalopathy, tremors, speech and motor problems and delirium, which was severe in 12% of cases and fatal in three patients. Other severe adverse events included infections (19%) and prolonged blood cell deficiencies (31%).

Breyanzi will be custom-produced for each patient at Bristol-Myers Squibb's cellular immunotherapy manufacturing facility in Bothell, Washington. The turnaround time from collection of a patients original T cells to infusion of the modified CAR-T cells is expected to be around 24 days.

Breyanzi can be administered on an inpatient or outpatient basis. Hospitals and outpatient clinics are required to follow a risk evaluation and mitigation strategy, and staff will be trained to manage CRS and neurological toxicity. Bristol-Myers Squibb will offer patients wearable technology to track their temperature through a smartphone during the post-infusion monitoring period, as fever can be an early indicator of emerging side effects.

"In TRANSCEND NHL 001, Breyanzi produced sustained responses in a significant proportion of patients with relapsed or refractory large B-cell lymphoma," principal investigator Jeremy Abramson, MD, MMSc, of Massachusetts General Hospital said in the Bristol-Myers Squibb press release. "TRANSCEND also demonstrated feasibility of outpatient administration, which is meaningful for patients, physicians and the healthcare system"

Another cohort of the TRANSCEND NHL 001 trial is evaluating Breyanzi for people with mantle cell lymphoma (MCL). It is also being studied for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma in the Phase I/II TRANSCEND CLL 004 study (NCT03331198). As reported at the American Society of Hematology (ASH) Annual Meeting in December, 66% of people with MCL achieved complete responses, as did 46% of CLL patients treated with Breyanzi alone and 63% of those treated with Breyanzi plus Imbruvica (ibrutinib).

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