Dana-Farber to offer first CAR T-cell therapy for mantle cell lymphoma after FDA approval

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Today's Food and Drug Administration (FDA) approval of the first CAR T-cell therapy for mantle cell lymphoma (MCL) represents a key advance for patients with relapsed or treatment-resistant forms of the disease, say Dana-Farber Cancer Institute investigators who helped conduct the decisive clinical trial of the therapy. Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) will be a certified treatment center for the therapy, known as Tecartus (brexucabtagene autoleucel, formerly KTE-X19).

Approval of Tecartus was based on the results of the ZUMA-2 clinical trial, which involved 74 adult patients with mantle cell lymphoma that had relapsed or become resistant to several prior lines of therapy. In the trial, 87% of participants responded to a single infusion of the agent, including 62% who achieved a complete response, or disappearance of all signs of their cancer.

"This is an incredibly exciting advancement in the treatment of mantle cell lymphoma, which is historically an incurable lymphoma with relatively short survival when chemotherapy stops working," said Caron Jacobson, MD, Medical Director of the Immune Effector Cell Therapy Program at Dana-Farber and an investigator involved in the trial. "The responses seen in the ZUMA-2 trial in very high risk and heavily pretreated MCL patients are phenomenal and although longer follow-up is needed, many persist beyond the one-year mark suggesting that this therapy has the potential to make a substantial impact on the natural history of this disease."

Like all CAR (Chimeric Antigen Receptor) T-cell therapies, Tecartus is made by collecting some of a patient's disease-fighting T cells and genetically modifying them to produce certain protein receptors on their surface. When injected back into the patient, the genetically enhanced CAR T-cells are better able to track down and attack cancer cells throughout the body.

FDA approval means Tecartus can now be used as part of standard treatment for adult patients with mantle cell lymphoma that has either relapsed or does not respond to other treatments.

Mantle cell lymphoma is a rare form of non-Hodgkin lymphoma that arises in cells originating in the "mantle zone" of the lymph node—a ring of cells surrounding an area where antibody-making B cells grow and mature. It typically affects men over the age of 60 and is treated with chemotherapy often in combination with other agents. Younger patients who relapse after initial therapies may undergo a stem cell transplant. While treatment of the disease has improved markedly, many patients have had few options once their disease stops responding to existing therapies.

DF/BWCC provides all FDA approved CAR T-cell therapies, including Kymriah and Yescarta. Clinical trials of CAR T-cell therapy for blood cancers such as other types of lymphoma, multiple myeloma, and leukemia are underway at DF/BWCC, and include trials of CAR T-cell therapy earlier in treatment, and in combination with other immunotherapies.

Provided by Dana-Farber Cancer Institute