FDA approves CAR T therapy for specific B-cell lymphomas, 1/18

January 2018—Kite Pharma announced that the FDA has approved Yescarta (axicabtagene ciloleucel), a cellbased gene therapy, to treat adult patients with certain types of large B-cell lymphoma who have not responded to or who have relapsed after at least two other kinds of treatment. Yescarta, a chimeric antigen receptor T cell therapy, is the second gene therapy approved by the FDA and the first for certain types of non-Hodgkin's lymphoma.

Each dose of Yescarta is a customized treatment created using a patient's own immune system to help fight the lymphoma. The patient's T-cells are collected and genetically modified to include a new gene that targets and kills the lymphoma cells. Once the cells are modified, they are infused back into the patient.

In the ZUMA-1 pivotal trial, Kite demonstrated a 99 percent manufacturing success rate with a median manufacturing turnaround time of 17 days, which is important to patients given the potential for rapid disease progression in this population.

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