Investigational CAR T Therapy: Researching a New Path for Cancer Treatment [1]

Discovery [2]

It’s hard to believe that less than five years ago, the first pediatric patient received CTL019 in a clinical trial at the Children’s Hospital of Philadelphia.

Investigational CAR T therapies such as CTL019 have made significant strides over the past several years as we’ve learned more about their potential through clinical trials. Novartis became the first major pharmaceutical company to invest in investigational CAR T therapy when it partnered with the University of Pennsylvania to investigate their potential in a variety of types of cancer in 2012. Two short years later, the US Food and Drug Administration
designated CTL019 as a Breakthrough Therapy for the treatment of pediatric and adult patients with relapsed/refractory acute lymphoblastic leukemia (r/r ALL), and since then we’ve seen developments continue to unfold in our research.

An analysis of a global registration trial investigating CTL019 in pediatric and young adults with r/r ALL called ELIANA was presented at this year’s American Society of Hematology (ASH) meeting. This pivotal Novartis study reached its primary endpoint, with 82% (41 of 50) of pediatric and young adult patients with r/r ALL achieving complete remission or complete remission with incomplete blood count recovery in the first global registration CAR T cell trial. Forty-eight percent of patients in the trial experienced grade 3 or 4 cytokine release syndrome (CRS), a known complication of the investigational therapy that may occur when the engineered cells become activated in the patient's body. This study builds on previous findings in this disease area from a US multi-center setting (ENSIGN).

CTL019 is produced in a state-of-the-art manufacturing facility in Morris Plains, NJ for its clinical trial program. CTL019 is investigational and has not been approved by the US Food and Drug Administration or other regulatory authorities. Efficacy and safety have not been established. There is no guarantee that CTL019 will become commercially available.

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