LymphomaHub

DLBCL

The FDA grants CTL019 Breakthrough Therapy Designation for adult patients with relapsed/refractory Diffuse Large B-Cell Lymphoma

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On 18th April 2017, CTL019 (also known as tisagenlecleucel) was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with R/R DLBCL who have failed two or more previous therapies.

Novartis' CTL019 is an investigational Chimeric Antigen Receptor (CAR) T-cell therapy and the Breakthrough Therapy Designation is based on early data from the phase II, single arm, multicenter JULIET study (NCT02445248). The trial is aiming to assess the safety and efficacy of CTL019 in adult patients with R/R DLBCL, it has an estimated enrollment of 130 patients, and the estimated primary completion date is January 2024.

CTL019 already holds Breakthrough Therapy Designation for pediatric and young adult patients with R/R B-cell Acute Lymphoblastic Leukemia (ALL).

Reference:

1. Sector Publishing Intelligence. Novartis CAR-T cell therapy CTL019 receives FDA Breakthrough Therapy designation for treatment of adult patients with r/r DLBCL. 2017 Apr 18. http://www.sectorpublishingintelligence.co.uk/news/1693895/novartis+cart+cell+therapy+ctl019+receives+fda+breakthrough+therapy+designation+for+treatment+of+adult+patien . [Accessed 2017 Apr 18].