

CAR-T Long Term Follow Up (LTFU) Study

Last Update: Mar 04, 2025

Long Term Follow-Up of Patients Exposed to Lentiviral-Based CAR T-Cell Therapy

ClinicalTrials.gov Identifier:

[NCT02445222](#)

Novartis Reference Number:CCTL019A2205B

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

Per Health Authorities guidelines for gene therapy medicinal products that utilize integrating vectors (e.g. lentiviral vectors), long term safety and efficacy follow up of treated patients is required. The purpose of this study is to monitor all patients exposed to CAR-T therapy for 15 years following their last CAR-T (e.g. CTL019) infusion to assess the risk of delayed adverse events (AEs), monitor for replication competent lentivirus (RCL) and assess long-term efficacy, including vector persistence. Patients are enrolled following completion or early discontinuation from a Novartis sponsored or supported study of CAR T-Cell treatment. Patients will be followed for 15 years post treatment from the last treatment. They will be monitored for safety and efficacy within the primary treatment protocols for the protocol defined duration. Patients can drop off treatment protocols at any time to enter this long term Follow up study. Patients discontinuing from the primary treatment protocols for any reason will be enrolled in this long term follow up (LTFU). This will allow collecting data on long term safety and efficacy (as applicable) as mandated by the health authorities of all patients treated with CAR-T therapy within the concept of a single protocol.

Collection of such long term effects of CAR-T cell therapy will help to further define the risk-benefit profile of CAR-T Therapies.

Condition

Long Term Safety of Patients Receiving CAR-T in an Eligible Clinical Trial or Managed Access Program

Phase

Phase3

Overall Status

Recruiting

Number of Participants

1400

Start Date

Jan 05, 2016

Completion Date

Feb 22, 2036

Gender

All

Age(s)

0 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Genetic

Previously treated CAR-T patients

Lentiviral-based CAR-T cell therapy

Eligibility Criteria

Inclusion Criteria:

- * All patients who have received a CAR-T therapy and completed or discontinued early from a Novartis sponsored treatment protocol that utilized CAR-T cells or from any CAR-T trial sponsored by the University of Pennsylvania with which Novartis has a contractual agreement to co-develop the CAR technology.
- * Patients who have provided informed consent for the long term follow up study prior to their study participation .

Exclusion Criteria:

- * There are no specific exclusion criteria for this study.

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