Effectiveness and Safety of Tisagenlecleucel Therapy in Brazilian Patients With B-lymphocyte Malignancies

Last Update: May 03, 2024
Effectiveness and Safety of Tisagenlecleucel Therapy in Brazilian Patients With B-lymphocyte Malignancies: a 15-year Prospective Registry Study on Three Cohorts.
ClinicalTrials.gov Identifier:
NCT05541341
Novartis Reference Number:CCTL019BBR02
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

This will be a multicenter, national, non-interventional, prospective cohort study Eligible participants will be pediatric (\<18 years) and adult patients (aged 18 years or older) with B-cell malignancies who have received tisagenlecleucel through the commercial setting or out-of-specification (OOS) use in Brazil. We will collect data prospectively and complement missing information with retrospective data collection, when necessary. It is anticipated that approximately 200 patients will be enrolled in the cohort over 5 years divided among the study indications.

Since this is a non-interventional study, no administration of study drug or application of questionnaires will be mandated by this protocol. The study will consist of a "Pre-infusion" and a "Post infusion follow-up period" for up to 15 years post tisagenlecleucel infusion. All patients will be followed until death or last scheduled visit, whichever comes first.

For the study, "pre-infusion" and "follow-up post infusion" phases are defined as:

* "Pre-infusion" will consist of the patient's information from the time of diagnosis untiljust prior to infusion with tisagenlecleucel.
* "Follow-up Post infusion" information will comprise any information from the infusionof tisagenlecleucel onwards.

Condition
Diffuse Large B-cell Lymphoma, Acute Lymphoblastic Leukemia, Follicular Lymphoma
Overall Status
Recruiting
Number of Participants
200
Start Date
Nov 24, 2023

Gender
All
Age(s)
- 100 Years (Child, Adult, Older Adult)

Interventions

Other

tisagenlecleucel

Prospective observational study. There is no treatment allocation. Patients prescribed with tisagenlecleucel in the commercial setting or out-of-specification (OOS) are eligible to enroll into this study

Eligibility Criteria

Inclusion Criteria:

Patients eligible for inclusion in this study must meet the following criteria:

1. Patients who receive tisagenlecleucel infusion in the commercial setting or out-of-specification (OOS) use, AND
2. Signed informed consent must be obtained prior to participation in study, AND

For ALL participants:
3. Patients of any gender aged 0-17 years (named as pediatric) with relapsed/ refractory B-cell ALL diagnosis that received tisagenlecleucel infusion, OR
4. Patients of any gender, aged 18-25 years (named as adults) - with relapsed/ refractory B-cell ALL diagnosis that received tisagenlecleucel infusion, OR

For DBLCL and FL participants:
5. Patients of any gender aged 18 years or older, who have been diagnosed with relapsed/ refractory Diffuse Large B-cell Lymphoma and received tisagenlecleucel infusion.

Exclusion Criteria:

1. Patients who did not consent to data collection.
2. Patients who received tisagenlecleucel infusion as part of any interventional clinical trial.

Brazil

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05541341*

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