Study of Out of Specification for Tisagenlecleucel

Last Update: Jan 24, 2025
A Phase IIIb Study of the Safety and Efficacy of Tisagenlecleucel Out of Specification for Commercial Release in Patients Who Are Consistent With the Label Indication
ClinicalTrials.gov Identifier:
NCT04094311
Novartis Reference Number:CCTL019B2302
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 study will evaluate the safety of tisagenlecleucel that is out of specification(OOS) for release as commercial product. Specifically, this study will evaluate the safety of CTL019 in the patients treated within the approved label by Japan Health Authority in Part 2. Only for Part 1, in addition to safety, key efficacy of CTL019 will also be evaluated. This is a single-arm, open-label, multicenter, interventional Phase IIIb study in pediatric/young adult patients with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (pALL) and adult patients with r/r large B-cell lymphoma (LBCL) including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high-grade B cell lymphoma, and DLBCL arising from follicular lymphoma for Part 1 and and r/r ALL and r/r non-Hodgkin's lymphomas (NHL) for Part 2

Patients whose final manufactured tisagenlecleucel patient-specific batch does not meet the approved local commercial release specifications are eligible for inclusion. Each case will be individually assessed and approved by the Novartis manufacturing facility and the Novartis global medical team (including Patient Safety). Following a single infusion of CTL019, the patient will be followed for 3 months for Part 1, and 1 day for Part 2.

Condition
B-cell Acute Lymphoblastic Leukemia, Diffuse Large B-cell Lymphoma
Phase
Phase3
Overall Status
Recruiting
Number of Participants
200
Start Date
Nov 21, 2019
Completion Date
Mar 31, 2026
Gender
All
Age(s)

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

Interventions

Biological

CTL019

A single intravenous (i.v.) infusion of CAR-positive viable T cells.

Eligibility Criteria

Key inclusion criteria:

* Signed informed consent/assent must be obtained for this study prior to participation in the study.
* Patients for whom the final manufactured tisagenlecleucel product does not meet the commercial release specifications.
* Not excluded from commercial manufacturing under the Health Authority-approved tisagenlecleucel prescribing information for their respective country/region.
* OOS material has not been deemed to pose an undue safety risk to the patient.
* Patient is suffering from a serious or life-threatening disease or condition.
* Repeat leukapheresis is not clinically appropriate per the investigator assessment.

Key exclusion criteria:

For part 1, patients meeting any of the following criteria are not eligible for inclusion in this study:

* Human immunodeficience virus (HIV) positive patients.
* Patients with active replication of Hepatitis B virus (HBV) or Hepatitis C virus (HCV).
* Patients with primary central nervous system (CNS) lymphoma.
* History of hypersensitivity to any drugs or metabolites of similar chemical classes as tisagenlecleucel.
* Uncontrolled active infection or inflammation.
* Any medical condition identified by the investigator that may impact the assessment of the safety or efficacy outcomes in relation to study treatment.
* Pregnant or nursing (lactating) women. For part 2, exclusion criteria are not set; however, administration should be performed in accordance with the latest versions of the package insert of CTL019.

Japan

Novartis Investigative Site

Recruiting

Gifu-city,Gifu,501-1194,Japan

Novartis Investigative Site

Recruiting

Setagaya-ku,Tokyo,157-8535,Japan

Novartis Investigative Site

Recruiting

Nagasaki-city,Nagasaki,852-8501,Japan

Novartis Investigative Site

Recruiting

Bunkyo ku,Tokyo,113-8431,Japan

Novartis Investigative Site

Recruiting

Kita-gun,Kagawa,761-0793,Japan

Novartis Investigative Site

Recruiting

Niigata,951 8520,Japan

Novartis Investigative Site

Recruiting

Osaka-city,Osaka,541-8567,Japan

Novartis Investigative Site

Recruiting

Sapporo city,Hokkaido,060 8648,Japan

Novartis Investigative Site

Recruiting

Shinjuku-ku,Tokyo,160 8582,Japan

Novartis Investigative Site

Recruiting

Yufu,Oita,879-5593,Japan

Novartis Investigative Site

Recruiting

Bunkyo ku,Tokyo,113-8677,Japan

Novartis Investigative Site

Recruiting

Yokohama-city,Kanagawa,236-0004,Japan

Novartis Investigative Site

Recruiting

Osaka,545-8586,Japan

Novartis Investigative Site

Recruiting

Osaka-city,Osaka,543-8555,Japan

Novartis Investigative Site

Recruiting

Aomori,030 8553,Japan

Novartis Investigative Site

Recruiting

Sapporo,Hokkaido,060-8543,Japan

Novartis Investigative Site

Recruiting

Kurashiki,Okayama,710-8602,Japan

Novartis Investigative Site

Recruiting

Bunkyo-ku,Tokyo,113-8519,Japan

Novartis Investigative Site

Recruiting

Nagoya-city,Aichi,467-8602,Japan

Novartis Investigative Site

Recruiting

Saitama,330 8777,Japan

Novartis Investigative Site

Recruiting

Kyoto-city,Kyoto,602-8566,Japan

Novartis Investigative Site

Recruiting

Suita,Osaka,565 0871,Japan

Novartis Investigative Site

Recruiting

Chiba,2608677,Japan

Novartis Investigative Site

Recruiting

Kobe,Hyogo,650-0047,Japan

Novartis Investigative Site

Recruiting

Okayama-city,Okayama,700-8558,Japan

Novartis Investigative Site

Recruiting

Chuo ku,Tokyo,104 0045,Japan

Novartis Investigative Site

Recruiting

Nagoya,Aichi,466 8560,Japan

Novartis Investigative Site

Recruiting

Wakayama,641-8510,Japan

Novartis Investigative Site

Recruiting

Tsu-city,Mie,514-8507,Japan

Novartis Investigative Site

Recruiting

Izumo-city,Shimane,693 8501,Japan

Novartis Investigative Site

Recruiting

Hiroshima,734-8551,Japan

Novartis Investigative Site

Recruiting

Nishinomiya,Hyogo,663 8501,Japan

Novartis Investigative Site

Recruiting

Izumi-city,Osaka,594-1101,Japan

Novartis Investigative Site

Recruiting

Fuchu,Tokyo,183-8524,Japan

Novartis Investigative Site

Recruiting

Toon city,Ehime,791-0295,Japan

Novartis Investigative Site

Recruiting

Sendai city,Miyagi,980 8574,Japan

Novartis Investigative Site

Recruiting

Hamamatsu,Shizuoka,431-3192,Japan

Novartis Investigative Site

Recruiting

Kumamoto,860-8556,Japan

Novartis Investigative Site

Recruiting

Tsukuba,Ibaraki,305-8576,Japan

Novartis Investigative Site

Recruiting

Izumisano-city,Osaka,598-8577,Japan

Novartis Investigative Site

Recruiting

Fukuoka city,Fukuoka,812-8582,Japan

Novartis Investigative Site

Recruiting

Minato-ku,Tokyo,105-8471,Japan

Novartis Investigative Site

Recruiting

Matsumoto,Nagano,390-8621,Japan

Novartis Investigative Site

Recruiting

Bunkyo ku,Tokyo,113 8655,Japan

Novartis Investigative Site

Recruiting

Kanazawa,Ishikawa,920 8641,Japan

Novartis Investigative Site

Recruiting

Kyoto,606 8507,Japan

Novartis Investigative Site

Recruiting

Osaka Sayama,Osaka,589 8511,Japan

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +81337978748
Email:

Novartis Pharmaceuticals

Phone: +41613241111
Email: Novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct04094311*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT04094311
2. #trial-eligibility
3. tel:+81337978748
4. mailto:
5. tel:+41613241111
6. mailto:Novartis.email@novartis.com