A Phase III Trial Comparing Tisagenlecleucel to Standard of Care (SoC) in Adult Participants With r/r Follicular Lymphoma

Last Update: May 30, 2025
A Randomized, Open-label, Multi-center Phase III Trial Comparing Tisagenlecleucel to Standard of Care in Adult Participants With Relapsed or Refractory Follicular Lymphoma (FL)
ClinicalTrials.gov Identifier:
NCT05888493
Novartis Reference Number:CCTL019E2301
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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 trial will compare tisagenlecleucel to standard of care in adult participants with relapsed or refractory (r/r) follicular lymphoma. The purpose of this phase III study is to verify the clinical benefit of tisagenlecleucel for the treatment of r/r FL by comparing the tisagenlecleucel treatment strategy to standard of care therapy in patients with r/r FL after two or more lines of systemic therapy, with progression-free survival (PFS) as the primary endpoint.

The primary objective is to demonstrate superiority of the tisagenlecleucel treatment strategy over standard of care (SOC) therapy with respect to progression-free survival (PFS) determined by blinded independent review committee (BIRC) based on the Lugano response criteria.

Participants randomized to Arm A (tisagenlecleucel treatment) will receive a single infusion of 0.6 to 6 x 10\^8 CAR-positive viable T-cells.

Participants randomized to Arm B (Standard of Care) will receive R2 or R-CHOP based on investigator choice and this has to be determined prior to randomization.

Condition
Follicular Lymphoma (FL)
Phase
Phase3
Overall Status
Recruiting
Number of Participants
108
Start Date
Oct 02, 2023
Completion Date

Jan 18, 2031
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Corticosteroids and/or Radiation (Bridging therapy)

Corticosteroids and/or Radiation
Drug

Lenalidomide and rituximab (R2) in 28-day cycles for up to 12 cycles.

Lenalidomide 20 mg daily on days 1-21 for up to 12 cycles Rituximab 375 mg/m2 IV on days 1, 8, 15, and 22 of cycle 1 and day 1 of cycles 2-5
Drug

Lymphodepleting chemotherapy

Fludarabine (25 mg/m\^2 intravenously \[i.v.\] daily for 3 doses) OR Cyclophosphamide (250 mg/m\^2 i.v. daily for 3 doses starting with the first dose of fludarabine). OR Bendamustine 90 mg/m\^2 i.v. daily for 2 days (If there was previous grade IV hemorrhagic cystitis with cyclophosphamide, or the participant demonstrated resistance to a previous cyclophosphamide-containing regimen)
Drug

Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone or prednisolone (R-CHOP) in 21-day cycles for 6 to 8 cycles

Rituximab 375 mg/m2 i.v. on day 1 Cyclophosphamide 750 mg/m2 i.v. day 1 Doxorubicin 50 mg/m2 i.v. day 1 Vincristine 1.4 mg/2 (capped at 2 mg) i.v. day 1 Prednisone or prednisolone 40 mg/m2 PO days 1-5
Biological

Tisagenlecleucel

Tisagenlecleucel is a solution for infusion of 0.6 to 6 x 10\^8 CAR-positive viable T-cells taken intravenously (i.v.).

Eligibility Criteria

Inclusion Criteria:

1. Age ≥ 18 years at the date of signing the informed consent form.
2. Follicular lymphoma grade 1, 2, or 3A confirmed histologically after latest relapse (local assessment).
3. Relapsed or refractory disease after a second or later line of systemic therapy including an anti-CD20 antibody and an alkylating agent.
4. Disease that is both active on Positron emission tomography (PET) scan (defined as a score of 4 or 5 on

the Deauville 5-point scale) and measurable on Computed tomography (CT) scan.
5. ECOG performance status of 0, 1 or 2 at screening.
6. Adequate hematologic, renal, hepatic and pulmonary organ function at screening.
7. Must meet the institutional criteria to undergo leukapheresis (unless historical leukapheresis is available).
8. Must be eligible for treatment with the selected standard of care regimen.

Exclusion Criteria:

1. Follicular lymphoma grade 3B or evidence of histologic transformation.
2. Prior treatment with anti-CD19 therapy, gene therapy, or adoptive T-cell therapy.
3. Active CNS involvement by malignancy.
4. Clinically significant active infection, presence of Human immunodeficiency virus (HIV) antibody or active hepatitis B or C.
5. Active neurological autoimmune or inflammatory disorders (e.g., Guillain-Barré syndrome).
6. Investigational medicinal product within the last 30 days or five half-lives (whichever is longer) prior to randomization.
7. Clinically significant cardiovascular conditions such as acute coronary syndrome, significant cardiac arrhythmias, heart failure or decreased LVEF.

Other protocol defined inclusion/exclusion criteria may apply

Australia

Novartis Investigative Site

Recruiting

Clayton,Victoria,3168,Australia

Novartis Investigative Site

Recruiting

Camperdown,New South Wales,2050,Australia

Novartis Investigative Site

Recruiting

Melbourne,Victoria,3004,Australia

Novartis Investigative Site

Recruiting

Nedlands,Western Australia,6009,Australia

Austria

Novartis Investigative Site

Recruiting

Salzburg,5020,Austria

Novartis Investigative Site

Recruiting

Linz,4020,Austria

Canada

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