A Study of Rapcabtagene Autoleucel in Systemic Lupus Erythematosus (SLE) Patients With Active, Refractory Lupus Nephritis (LN)

Last Update: Mar 18, 2025
A Phase 2, Adaptive, Randomized, Open-label, Assessor-blinded Active-controlled Study to Evaluate the Efficacy and Safety of Rapcabtagene Autoleucel Versus Standard of Care in Patients Suffering From Systemic Lupus Erythematosus (SLE) With Active, Refractory Lupus Nephritis (LN).
ClinicalTrials.gov Identifier:
NCT06581198
Novartis Reference Number:CYTB323J12201
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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

The purpose of this study is to evaluate the efficacy and safety of rapcabtagene autoleucel (administered once following lymphodepletion) versus Standard of Care (SOC) in patients with systemic lupus erythematosus (SLE) with active, refractory lupus nephritis (LN). This is a Phase 2, adaptive, two-year, randomized, assessor-blinded, active controlled study:

* Part A: Participants suffering from systemic lupus erythematosus (SLE) with active, refractory LN will be randomized to Regimen 1, Regimen 2, or SOC.
* Part B: Participants suffering from SLE with active, refractory LN will be randomized to the selected regimen from Part A or SOC.

The study will consist of two periods:

* A screening period lasting up to 6 weeks, and
* A randomized treatment period and primary follow-up period lasting up to 104 weeks.

After end of study (EOS), participants who received rapcabtagene autoleucel infusion will enter a long-term follow-up (LTFU) period lasting up to 15 years after rapcabtagene autoleucel infusion. This LTFU will be described in a separate study protocol.

Condition
Lupus Erythematosus, Systemic, Lupus Nephritis
Phase
Phase2
Overall Status
Recruiting
Number of Participants

144
Start Date
Sep 04, 2024
Completion Date
Jun 13, 2030
Gender
All
Age(s)
18 Years - 65 Years (Adult, Older Adult)

Interventions

Biological

rapcabtagene autoleucel Regimen 1

single infusion of rapcabtagene autoleucel
Biological

rapcabtagene autoleucel Regimen 2

single infusion of rapcabtagene autoleucel
Other

Standard of Care

The treatment regimen must be in line with KDIGO guidelines for treatment of class III/IV LN.

Eligibility Criteria

Key Inclusion Criteria:

* Men and women with SLE, aged \>= 18 years and =\< 65 years at screening, fulfilling the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) classification criteria for SLE at screening.
* Participant must be positive for at least one of the following autoantibodies at screening: antinuclear antibodies (ANA) at a titer of \>= 1:80 (on HEp-2 cells or an equivalent positive test), or anti-dsDNA (above the ULN); or anti-Sm (above the ULN) as determined by a central laboratory.
* Active lupus nephritis without signs of significant chronicity
* SLEDAI-2K Criteria at screening: SLEDAI-2K score \>= 6 points (Gladman et al 2002, Touma et al 2011), excluding points attributed to "fever", "lupus headache", "alopecia", and "organic brain syndrome".
* Inadequate response at screening to at least two LN treatment regimens

Key Exclusion Criteria:

* Any acute, severe lupus related-flare at screening that needs immediate treatment other than pulse GCs and/or makes the immunosuppressive washout impossible and, thus, makes the participant ineligible for CD19 CAR-T therapy
* Inadequate organ function during screening and prior to randomization
* History or current diagnosis of ECG or cardiac abnormalities indicating significant risk of safety for

participants prior to randomization
* Human immunodeficiency virus (HIV) positivity at screening.
* Acute or chronic infection with hepatitis B (HBV) or hepatitis C (HCV) at screening.
* Evidence of active or latent tuberculosis.
* Grade 2 or higher thromboembolic event in the past 4 weeks prior to screening.
* Vaccination (including with live attenuated vaccines) not completed at least 6 weeks prior to randomization.

Other protocol-defined inclusion/exclusion criteria may apply.

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