An Ascending Dose Study of PIT565 in Participants With Systemic Lupus Erythematosus (SLE).

Last Update: Jun 05, 2025
A Phase Ib, Open-label, Ascending Dose Study With Step-up Doses to Assess Safety, Tolerability, and Pharmacokinetics of PIT565 in Participants With Systemic Lupus Erythematosus (SLE).
ClinicalTrials.gov Identifier:
NCT06335979
Novartis Reference Number:CPIT565B12101
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

The purpose of the study is to determine the safety, tolerability, and pharmacokinetics of PIT565 in participants with SLE This is an open-label, ascending dose, uncontrolled study in participants with SLE systemic lupus erythematosus (SLE). PIT565 will be administered subcutaneously (s.c.) following premedication.

Up to 8 cohorts are planned. Every cohort will have 3 sentinel participants and, depending on safety as well as observed biological activity, may have up to 3 additional optional participants (up to 6 participants per cohort). The decision to escalate the dose from one cohort to the next will be based both on safety and PD data. After the identification of a dose level that has been declared safe and has induced predefined B cell depletion in 100% of the participants (candidate dose level), the cohort from this candidate dose level can optionally be enriched with 6 additional participants (up to a total of 12 participants).

Condition
Systemic Lupus Erythematosus, SLE
Phase
Phase1
Overall Status
Recruiting
Number of Participants
54
Start Date
Oct 08, 2024
Completion Date
Jul 09, 2027
Gender
All
Age(s)
18 Years - 75 Years (Adult, Older Adult)

Interventions

Interventions

Drug

PIT565

In each cohort, there will be 3 sentinel participants. Additional participants might be added depending on safety and observed biological activity.

Eligibility Criteria

Inclusion Criteria:

* Diagnosis of SLE according to the 2019 ACR/EULAR criteria
* Documentation of SLE autoantibodies
* Active SLE disease, as demonstrated by a SLEDAI-2K ≥ 4 at screening
* Failure to respond to standard-of-care medicines for the treatment of SLE as detailed in the protocol
* Immunization against pneumococcus, influenza, and COVID-19

Exclusion Criteria:

* Severe SLE-related organ damage dysfunction or life-threatening disease at screening.
* Any acute, severe lupus-related flare during screening that needs immediate treatment such as acute CNS lupus (e.g., psychosis, epilepsy) or catastrophic antiphospholipid syndrome.
* Presence of severe lupus kidney disease as defined by worsening proteinuria or estimated glomerular filtration rate (eGFR) which in the opinion of the Investigator requires immune-suppressive induction or maintenance treatment at screening.
* History or current diagnosis of ECG or cardiac abnormalities indicating a significant risk of safety for participants.
* Use of prohibited medication defined in the protocol.
* Clinically significant active, opportunistic, chronic or recurrent infection (including, HIV, HBV, HCV) confirmed one month prior to or during screening.
* Serious medical illness likely to interfere with participation in this clinical study.
* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant from menarche until becoming post-menopausal, unless they are using highly effective methods of contraception

Other protocol defined inclusion/exclusion criteria may apply.

Bulgaria

Novartis Investigative Site

Recruiting

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China

Novartis Investigative Site

Recruiting

Beijing,100191,China

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06335979*

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