Safety, Efficacy and Tolerability of Ianalumab Versus Placebo, Combination With SoC Therapy, in Participants With Active Lupus Nephritis

Last Update: Jan 27, 2025

A Randomized, Double-blind, Parallel Group, Placebo-controlled, Multicenter Phase 3 Trial to Evaluate Efficacy, Safety and Tolerability of Ianalumab on Top of Standard-of-care Therapy in Participants With Active Lupus Nephritis (SIRIUS-LN).

ClinicalTrials.gov Identifier:
NCT05126277

Novartis Reference Number:CVAY736K12301

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 trial will evaluate efficacy, safety, and tolerability of subcutaneous (s.c.) ianalumab given every 4 weeks (q4w) or every 12 weeks (q12w) compared to placebo, in combination with SoC, in adult participants with active LN This trial will evaluate the efficacy, safety, and tolerability of subcutaneous (s.c.) ianalumab given every 4 weeks (q4w) or ianalumab given every 12 weeks (q12w) compared to placebo, in combination with SoC, in adult participants with active LN (ISN/RPS class III, IV active glomerulonephritis with or without co-existing class V features, or pure class V membranous). using the 2003 International Society for Nephrology (ISN)/Renal Pathology Society (RPS) criteria).

Condition
Lupus Nephritis
Phase
Phase3
Overall Status
Recruiting
Number of Participants
420
Start Date
Jul 14, 2022
Completion Date
Jul 15, 2030
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Interventions

Drug

ianalumab s.c. q12w

ianalumab s.c. q12w in addition to SoC
Drug

ianalumab s.c. q4w

ianalumab s.c. q4w in addition to SoC
Drug

placebo s.c.

placebo s.c. q4w in addition to SoC

Eligibility Criteria

Inclusion Criteria:

Participants eligible for inclusion in this study must meet all of the following criteria:

* Adult male and female participants aged 18 years or older at the time of screening
* Weigh at least 35 kg at screening
* Have a confirmed clinical diagnosis of SLE according to European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) Systemic Lupus Erythematosus (SLE) classification criteria
* Have a positive anti-nuclear antibody (ANA) test result; ANA titer ≥ 1:80 at screening visit based on central or local laboratory result
* Active LN at screening, as defined by meeting the 3 following criteria:
* Renal biopsy within 6 months prior to screening period indicating ISN/RPS class III or IV active glomerulonephritis with or without co-existing class V features, or pure class V membranous LN. If no biopsy was performed within 6 months prior to screening period, a biopsy will need to be performed during the screening period after having met all other inclusion/exclusion criteria.
* UPCR ≥ 1.0 g/g on 24h urine collection at Screening
* eGFR ≥ 25mL/min/1.73 m2. Participants with eGFR \< 30 mL/min/1.73 m2 require renal biopsy during the screening period showing sclerosis in ≤ 50% of glomeruli
* Newly diagnosed participants as well as pre-treated LN participants (including refractory cases) can be included, as long as they are currently on, or willing to initiate SoC induction therapy for LN using MPA

* Induction therapy, as defined by treatment including both high dose corticosteroids and MPA, should be initiated prior to or on day of randomization
* Anti-malarial treatment at stable dosing prior to randomization is strongly recommended, in the absence of contraindications
* Participants on azathioprine treatment at Screening must be switched to MPA prior to randomization
* Receipt of at least one dose of pulse methylprednisolone i.v. (250 - 1000 mg per day up to 3000 mg cumulative dose) or equivalent for treatment of current episode of active LN within 60 days prior randomization. Participant who cannot take the pulse i.v. corticosteroid therapy should directly start on 0.8-1.0 mg/day (max 80mg/day) oral predniso(lo)ne.

* Able to communicate well with the Investigator to understand and comply with the requirements of the study

Exclusion Criteria:

Participants meeting any of the following criteria are not eligible for inclusion in this study:

* Severe renal impairment as defined by i.) presence of oliguria (defined as a documented urine volume \<400 mL/24 hrs) or ii.) End-Stage Renal Disease (ESRD) requiring dialysis or transplantation
* Sclerosis in \> 50% of glomeruli on renal biopsy
* Use of other investigational drugs within 5 half-lives of enrollment, or within 30 days or until the expected pharmacodynamic effect has returned to baseline. Use of certain Traditional Chinese Medicines
* Prior use of ianalumab (ever); or prior use other B cell depleting therapy within 36 weeks prior to randomization or if therapy was administered \< 36 weeks prior to randomization, B cell count less than the lower limit of normal or patient's own baseline value prior to having received an earlier B cell-depleting therapy
* Prior treatment with any of the following within 12 weeks prior to randomization

* Belimumab, telitacicept, abatacept, TNF-α mAb, immunoglobulins (i.v./s.c.) plasmapheresis
* Any other immuno-suppressants (i.v. or oral cyclophosphamide, calcineurin inhibitors, JAK inhibitors or other kinase inhibitors)
* Thalidomide treatment and/or methotrexate
* Combination of DMARDs
* Imidazole derivative (e.g., azathioprine, mizoribine) must be discontinued prior to starting treatment with MPA
* Receipt of more than 3000 mg i.v. pulse methylprednisolone (cumulative dose) within 12 weeks prior to randomization
* History of major organ transplant or hematopoietic stem cell/bone marrow transplant or are due to receive transplantation
* Any one of the following laboratory values at screening:

* Hemoglobin levels \< 8.0 g/dL (\< 5 mmol/L), or \< 7.0 g/dL (\< 4.3 mmol/L) if related to participant's SLE such as in active hemolytic anaemia
* Platelet count \< 25 x 1000/µL
* Absolute neutrophil count (ANC) \< 0.8 x 1000/µL
* Active viral, bacterial or other infections requiring intravenous or intramuscular treatment for clinically significant infection or history of recurrent clinically significant infection which in the opinion of the investigator will place the participant at risk for participation.
* History of known intolerance/hypersensitivity to MPA, oral corticosteroids, or any component of the study drug(s) or its excipients
* Receipt of live/attenuated vaccine within a 4-week period prior to randomization
* History of primary or secondary immunodeficiency, including a positive HIV test result
* History of malignancy of any organ system (other than localized basal cell carcinoma or squamous cell carcinoma of the skin or or in-situ cervical cancer), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases
* Any surgical, medical (e.g., uncontrolled hypertension, heart failure or diabetes), psychiatric or additional physical condition that the Investigator feels may jeopardize the participants in case of participation in this study
* Chronic infection with hepatitis B (HBV) or hepatitis C (HCV). Positive serology for hepatitis B surface antigen (HBsAg) excludes the participant
* Evidence of active tuberculosis (TB) infection (after anti-TB treatment, participants with history of TB may become eligible according to national local guidelines)
* Pregnant or nursing (lactating) women

* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 6 months after stopping of investigational medication
* Sexually active male participants, who do not agree to use barrier protection during intercourse with women of child-bearing potential while taking study treatment

Other protocol -defined Inclusion/Exclusion may apply.

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