Phase 3 Study to Evaluate Two Regimens of Ianalumab on Top of Standard-of-care Therapy in Patients With Systemic Lupus Erythematosus (SIRIUS-SLE 1)

Last Update: Mar 06, 2025
A Randomized, Double-blind, Parallel Group, Placebo-controlled Multicenter Phase 3 Study to Evaluate Efficacy, Safety and Tolerability of Two Regimens of Ianalumab on Top of Standard-of-care Therapy in Patients With Systemic Lupus Erythematosus (SIRIUS-SLE 1)
ClinicalTrials.gov Identifier:
NCT05639114
Novartis Reference Number:CVAY736F12301
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 trial will evaluate efficacy, safety and tolerability of two regimens of ianalumab compared to placebo, given as monthly or quarterly subcutaneous (s.c.) injection on top of standard-of-care (SoC) treatment in participants with active systemic lupus erythematosus (SLE). A randomized, double-blind, parallel group, placebo-controlled multicenter phase 3 study to evaluate efficacy, safety and tolerability of two regimens of ianalumab on top of standard-of-care therapy in patients with systemic lupus erythematosus (SIRIUS-SLE 1)

Condition
Systemic Lupus Erythematosus
Phase
Phase3
Overall Status
Recruiting
Number of Participants
406
Start Date
Mar 02, 2023
Completion Date
Apr 20, 2029
Gender
All
Age(s)
12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Ianalumab

ianalumab s.c. monthly or quarterly
Drug

Placebo

placebo s.c. monthly

Eligibility Criteria

Inclusion Criteria:

* Male and female participants aged 12 years or older at the time of screening, or limited to 18 years or older in European Economic Area countries and other countries where inclusion of participants below 18 years is not allowed.
* Diagnosis of systemic lupus erythematosus meeting the 2019 European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) SLE classification criteria at least 6 months prior to screening.
* Elevated serum titers at screening of anti-nuclear antibodies ≥ 1:80 as determined by a central laboratory with a SLE-typical fluorescence pattern.
* Currently receiving CS and/or anti-malarial treatment and/or another disease-modifying antirheumatic drug (DMARD) as specified in the protocol.
* SLEDAI-2K criteria at screening: SLEDAI-2K score ≥ 6 points, excluding points attributed to "fever", "lupus headache", "alopecia", and "organic brain syndrome"
* BILAG-2004 disease activity level at screening of at least 1 of the following:

* BILAG-2004 level 'A' disease in ≥ 1 organ system, Or
* BILAG-2004 level 'B' disease in ≥ 2 organ systems
* Weigh at least 35 kg at screening

Exclusion Criteria:

* Prior treatment with ianalumab
* History of receiving following treatment: I) high dose CS, calcineurin inhibitors, JAK or other kinase inhibitors or other DMARD (except as listed in inclusion criteria) administered within 12 weeks prior to screening. II) cyclophosphamide or biologics such as immunoglobulins (intravenous or s.c.), plasmapheresis, anti-type I interferon receptor biologic agents, anti-CD40 agents, CTLA4-Fc Ig or B-cell activating factor (BAFF)-targeting agents administered within 24 weeks prior to screening; belimumab administered within 12 weeks prior to screening. III) any B cell-depleting therapies, other than ianalumab administered within 36 weeks prior to randomization or as long as B cell count is less than the lower limit of normal or baseline value prior to receipt of B cell-depleting therapy (whichever is lower). IV) Traditional Chinese medicines administered within 30 days prior to randomization.
* Active viral, bacterial or other infections requiring intravenous or intramuscular treatment for clinically significant infection

* Chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV)
* Evidence of active tuberculosis infection
* History of primary or secondary immunodeficiency, including a positive human immunodeficiency virus (HIV) test result at screening
* Any one of the following abnormal laboratory values prior to randomization

* Platelets \< 25000/mm\^3 (\< 25 x 10\^3/µL)
* Hemoglobin (Hgb) \< 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
* Absolute neutrophil count (ANC) (\< 0.8 x 10\^3/ µL)
* Severe organ dysfunction or life-threatening disease at screening
* Presence of severe lupus kidney disease as defined by proteinuria above 2 g/day or equivalent using spot urine protein creatinine ratio, or serum creatinine greater than 2.0 mg/dL (176.84 µmol/L), or requiring immune-suppressive induction or maintenance treatment at screening
* Receipt of live/attenuated vaccine within a 4-week period before first dosing
* Any uncontrolled, co-existing serious disease, which in the opinion of the investigator will place the participant at risk for participation or interfere with evaluation for SLE-related symptoms
* Non-lupus conditions such as asthma, gout or urticaria, requiring intermittent or chronic treatment with systemic CS
* History of malignancy of any organ system other than localized basal cell carcinoma of the skin or in situ cervical cancer
* Pregnant or nursing (lactating) women.
* Women of child-bearing potential (WOCBP), defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception while on study treatment and for 6 months after stopping of investigational drug.
* Any surgical, medical, psychiatric or additional physical condition that may jeopardize participation in this study

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