

Phase 3 Extension Study to Evaluate Long-term Safety of Ianalumab in Participants With Systemic Lupus Erythematosus (SIRIUS-SLE Extension).

Last Update: May 06, 2025

A Randomized, Double-blind, Placebo-controlled Extension Study to Assess the Long-term Safety and Tolerability of Ianalumab in Patients With Systemic Lupus Erythematosus (SIRIUS-SLE Extension)

ClinicalTrials.gov Identifier:

[NCT06133972](#)

Novartis Reference Number: CVAY736F12301E1

[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 this study is to evaluate long-term safety and tolerability of Ianalumab in participants with systemic lupus erythematosus who have previously completed the treatment period in one of the two SIRIUS-SLE core studies (CVAY736F12301 or CVAY736F12302). The purpose of this extension study is to evaluate long-term safety and tolerability of Ianalumab administered s.c. monthly or quarterly, compared to monthly placebo, in adolescent and adult participants with anti-nuclear antibody (ANA)-positive systemic lupus erythematosus of moderate-to-severe disease activity, who have completed either CVAY736F12301 (SIRIUS-SLE 1) or CVAY736F12302 (SIRIUS-SLE 2) core studies.

Condition

Systemic Lupus Erythematosus

Phase

Phase3

Overall Status

Recruiting

Number of Participants

550

Start Date

May 21, 2024

Completion Date

Dec 23, 2031

Gender

All

Age(s)

12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Ianalumab

Ianalumab s.c. monthly Ianalumab s.c. quarterly

Drug

Placebo

Placebo s.c. monthly

Eligibility Criteria

Key Inclusion Criteria:

- * Signed informed consent prior to participation in the extension study. Parent or legal guardian's signed informed consent and child's assent, if appropriate, are required before any assessment is performed for participants <18 years of age. Of note, if the participant reaches age of consent (age as per local law) during the study, they will also need to sign the corresponding study Informed Consent Form (ICF) at the next study visit.
- * Participants must have participated in either one of the two SIRIUS-SLE core studies, CVAY736F12301 or CVAY736F12302, and have completed the treatment period through Week 60 without treatment discontinuation.
- * In the judgement of the investigator, participants must be expected to clinically benefit from continued study treatment.

Key Exclusion Criteria:

- * Use of prohibited therapies.
- * Active viral, bacterial or other infections requiring intravenous or intramuscular treatment for clinically significant infection which in the opinion of the investigator will place the participant at risk for participation.
- * Plans for administration of live vaccines during the study period.
- * Pregnant or nursing (lactating) women.
- * Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, refusing or unable to use highly effective methods of contraception while on study treatment and for 6 months after stopping of study drug (or longer if required by concomitant medications).
- * United States (and other countries, if locally required): sexually active males, unless they agree to use barrier protection during intercourse with women of child-bearing potential while taking study treatment.

Other protocol-defined inclusion/exclusion criteria may apply.

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