

# A Clinical Study to Evaluate Ianalumab in Participants With Diffuse Cutaneous Systemic Sclerosis

Last Update: Jan 27, 2025

A Randomized, Double-blind, Parallel Group, Placebo-controlled Multicenter Study to Evaluate Efficacy, Safety and Tolerability of Ianalumab in Participants With Diffuse Cutaneous Systemic Sclerosis

ClinicalTrials.gov Identifier:

[NCT06470048](#)

Novartis Reference Number: CVAY736S12201

[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 efficacy, safety and tolerability of s.c. Ianalumab administered in participants with diffuse cutaneous systemic sclerosis relative to placebo. The study consists of the following periods:

- \* Screening Period, with a duration of up to 6 weeks;
- \* Treatment Period 1, with a duration of 52 weeks;
- \* Treatment Period 2 (Open-label treatment), with a duration of 52 weeks;
- \* Post-treatment Follow-up Period, with a duration of at least 20 weeks post last dose and up to 2 years.

Condition

Diffuse Cutaneous Systemic Sclerosis

Phase

Phase2

Overall Status

Recruiting

Number of Participants

200

Start Date

Oct 09, 2024

Completion Date

Jul 15, 2030

Gender

All

Age(s)

18 Years - 70 Years (Adult, Older Adult)

## Interventions

Drug

## Ianalumab

subcutaneous (s.c.) injection as defined in the protocol

Drug

## Placebo

Ianalumab matching placebo subcutaneous (s.c.) injection as defined in the protocol

## Eligibility Criteria

Key Inclusion Criteria:

- \* Male and female participants  $\geq 18$  and  $\leq 70$  years (at the time of the screening visit).
- \* Diagnosis of systemic sclerosis, as defined by the 2013 American College of Rheumatology/ European League Against Rheumatism (ACR/EULAR) classification criteria for SSc (van den Hoogen et al 2013) and meet the dcSSc subset classification according to LeRoy (LeRoy 1988)
- \* Disease duration of  $\leq 60$  months (defined as time from the first non-Raynaud phenomenon manifestation, e.g., puffy hands, scleroderma, digital ulcers, arthralgia, dyspnea)
- \* mRSS units of  $\geq 15$  and  $\leq 45$  at the time of the screening visit
- \* Active disease that meets at least one of the following criteria at screening:
  - \* Disease duration of  $\leq 18$  months defined as time from the first non-Raynaud phenomenon manifestation
  - \* Increase in mRSS of  $\geq 3$  units compared with the most recent assessment performed within the previous 6 months
  - \* Involvement of one new body area and an increase in mRSS of  $\geq 2$  units compared with the most recent assessment performed within the previous 6 months
  - \* Involvement of two new body areas within the previous 6 months
  - \* Elevated acute phase reactants (ESR)  $\geq 30$  mm/hr or high-sensitivity C-reactive protein (hsCRP)  $\geq 6$  mg/dL)
  - \* Presence of interstitial lung disease (ILD) and ATA autoantibody positivity
  - \* Modified EUSTAR disease activity index (mDAI)  $\geq 2.5$
- \* Participant must be positive for at least one of the following autoantibodies:
  - \* anti-topoisomerase I (ATA) (also known as anti-SCL-70)
  - \* anti-RNA polymerase III (anti-RNAP3)
  - \* anti-nuclear antibody (ANA) ( $\geq 1:80$ ) Participants who are positive only for ANA (while being negative for both ATA /anti-RNAP3) will be limited to 30% of the overall randomized study population.

Key Exclusion Criteria:

- \* Rheumatic disease other than dcSSc, including limited cutaneous disease (lcSSc) or sine scleroderma at the screening visit. Secondary Sjogren's disease and scleroderma myopathy are not exclusionary.
- \* Positive anti-centromere antibody (ACA+) without positive ATA or anti-RNAP3 autoantibody result at the screening visit
- \* Previous improvement (decrease) in mRSS  $\geq 10$  units
- \* Pulmonary disease with FVC  $\leq 50\%$  of predicted or diffusing capacity of the lung for carbon monoxide

(DLCO, corrected for hemoglobin)  $\leq$  40% of predicted at the screening visit

\* WHO Functional Class 3 or higher assessment for pulmonary arterial hypertension (PAH, as defined on right heart catheterization), receiving IV therapy for PAH or evidence of other moderately severe pulmonary disease

\* Participants treated with cyclophosphamide within 12 weeks prior to Baseline.

\* Prior use of a B-cell depleting therapy other than ivalumab (e.g., rituximab, other anti-CD20 mAb, anti-CD22 mAb, or anti-CD52 mAb) 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)

\* Treatment with biologic agents, such as intravenous immunoglobulin or monoclonal antibodies, including marketed drugs, within 12 weeks or 5 half-lives (whichever is longer) prior to baseline visit, unless explicitly allowed in inclusion criteria

\* Treatment with any investigational agent within  $\leq$  4 weeks (or 5 half-lives of the investigational drug, whichever is longer) of the baseline visit

\* Use of anti-fibrotic agents including colchicine, D-penicillamine, pirfenidone, or tyrosine kinase inhibitors (e.g., nintedanib, nilotinib, imatinib, dasatinib) in the 4 weeks prior to baseline visit.

\* Previous treatment with chlorambucil, bone marrow transplantation or total lymphoid irradiation.

Other protocol-defined inclusion/exclusion criteria may apply.

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