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

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 \>= 18 and =\< 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 =\< 60 months (defined as time from the first non-Raynaud phenomenon manifestation, e.g., puffy hands, scleroderma, digital ulcers, arthralgia, dyspnea)
* mRSS units of \>= 15 and =\< 45 at the time of the screening visit
* Active disease that meets at least one of the following criteria at screening:

* Disease duration of =\< 18 months defined as time from the first non-Raynaud phenomenon manifestation
* Increase in mRSS of \>= 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 \>= 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) \>= 30 mm/hr or high-sensitivity C-reactive protein (hsCRP) \>= 6 mg/dL)
* Presence of interstitial lung disease (ILD) and ATA autoantibody positivity
* Modified EUSTAR disease activity index (mDAI) \> 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) (≥ 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 \> 10 units
* Pulmonary disease with FVC ≤ 50% of predicted or diffusing capacity of the lung for carbon monoxide

(DLCO, corrected for hemoglobin) ≤ 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 ianalumab (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 ≤ 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.

Austria

Novartis Investigative Site

Recruiting

Graz,8036,Austria

China

Novartis Investigative Site

Recruiting

Nanning,Guangxi,530021,China

Novartis Investigative Site

Recruiting

Chengdu,Sichuan,610041,China

Novartis Investigative Site

Recruiting

Zhejiang,315016,China

Novartis Investigative Site

Recruiting

Beijing,100191,China

Germany

Novartis Investigative Site

Recruiting

Wuerzburg,97080,Germany

Novartis Investigative Site

Recruiting

Berlin,13353,Germany

Greece

Novartis Investigative Site

Recruiting

Athens,115 21,Greece

Hungary

Novartis Investigative Site

Recruiting

Debrecen,4032,Hungary

India

Novartis Investigative Site

Recruiting

Jaipur,Rajasthan,302004,India

Novartis Investigative Site

Recruiting

Kochi,Kerala,682018,India

Novartis Investigative Site

Recruiting

Mumbai,Maharashtra,400078,India

Italy

Novartis Investigative Site

Recruiting

Roma,RM,00168,Italy

Novartis Investigative Site

Recruiting

Verona,VR,37134,Italy

Novartis Investigative Site

Recruiting

Ancona,AN,60126,Italy

Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,03080,Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,04763,Korea, Republic of

Novartis Investigative Site

Recruiting

Busan,49241,Korea, Republic of

Poland

Novartis Investigative Site

Recruiting

Bydgoszcz,85 168,Poland

Novartis Investigative Site

Recruiting

Warszawa,00-874,Poland

Portugal

Novartis Investigative Site

Recruiting

Vila Nova De Gaia,4434 502,Portugal

Spain

Novartis Investigative Site

Recruiting

Malaga,Andalucia,29010,Spain

Taiwan

Novartis Investigative Site

Recruiting

Changhua,50006,Taiwan

Novartis Investigative Site

Recruiting

Taoyuan,33305,Taiwan

Novartis Investigative Site

Recruiting

Taichung,40447,Taiwan

Thailand

Novartis Investigative Site

Recruiting

Khon Kaen,THA,40002,Thailand

Novartis Investigative Site

Recruiting

Bangkok,10400,Thailand

Turkey

Novartis Investigative Site

Recruiting

Ankara,06230,Turkey

Novartis Investigative Site

Recruiting

Ankara,06500,Turkey

Novartis Investigative Site

Recruiting

Istanbul,34093,Turkey

United States

West Tennessee Research Institute

Recruiting

Jackson,Tennessee,38305,United States

Jacob A. Aelion

Brittany Appleton

Phone: 731-664-7824
Email: bappleton@arthritisclinic.org

Sarasota Arthritis Res Ctr

Recruiting

Sarasota,Florida,34239,United States

Angi Gomez

Phone: 941-366-1244
Email: angi@arthritiscenters.net

Jaishree Manohar

Prolato Clinical Research Center

Recruiting

Houston,Texas,77054,United States

Michelle Eisenberg

Romeo Parada

Phone: 832-338-9118
Email: rparada@prolato.org

Arthritis and Rheumatology Ins

Recruiting

Allen,Texas,75013,United States

Kiran Khandelwal

Email: k.khandelwal@dfwarthritis.com

Megha Patel Banker

Clinical Res Of W Florida

Recruiting

Clearwater,Florida,33765,United States

Rodney Daniel

Sydney K Mullen

Phone: 727-466-0078
Email: smullen@crwf.com

Vietnam

Novartis Investigative Site

Recruiting

Ho Chi Minh,700000,Vietnam

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06470048*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06470048

2. #trial-eligibility
3. tel:731-664-7824
4. mailto:bappleton@arthritisclinic.org
5. tel:941-366-1244
6. mailto:angi@arthritiscenters.net
7. tel:832-338-9118
8. mailto:rparada@prolato.org
9. mailto:k.khandelwal@dfwarthritis.com
10. tel:727-466-0078
11. mailto:smullen@crwf.com
12. tel:+41613241111
13. mailto:novartis.email@novartis.com
14. tel:1-888-669-6682
15. mailto:novartis.email@novartis.com