Study to Assess Efficacy Safety and Tolerability of Remibrutinib in Adult Patients With Moderate to Severe Hidradenitis Suppurativa

Last Update: Mar 27, 2025

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Multicenter, Phase 3 Study Assessing the Efficacy, Safety, and Tolerability of 2 Doses of Remibrutinib Over a 68-week Treatment Period in Adult Patients With Moderate to Severe Hidradenitis Suppurativa

ClinicalTrials.gov Identifier:

NCT06840392

Novartis Reference Number:CLOU064J12302

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 establish the efficacy, safety, and tolerability of remibrutinib (LOU064) Dose A and Dose B compared to placebo in participants with moderate to severe hidradenitis suppurativa (HS). The total duration of the study is 76 weeks and consists of: Screening (up to 4 weeks), Treatment Period 1 (16 weeks, double-blind treatment with remibrutinib (Dose A or Dose B) or placebo, Treatment Period 2 (52 weeks, treatment with remibrutinib (Dose A or Dose B) and Safety Follow-Up (treatment-free follow-up for 4 weeks).

Participants who prematurely discontinue study treatment (either during Treatment Period 1 or Treatment Period 2) are encouraged to remain in the study. Participants who do not wish to remain in the study will enter a 4-week Safety Follow-Up period.

Condition

Hidradenitis Suppurativa

Phase

Phase3

Overall Status

Recruiting

Number of Participants

555

Start Date

Mar 20, 2025

Completion Date

Oct 20, 2028

Gender

All

Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Placebo 1

Placebo matching to remibrutinib Dose A (oral)
Drug

Placebo 2

Placebo matching to remibrutinib Dose B (oral)
Drug

Remibrutinib Dose A

Remibrutinib Dose A (oral)
Drug

Remibrutinib Dose B

Remibrutinib Dose B (oral)

Eligibility Criteria

Key Inclusion Criteria:

1. Male and female participants ≥ 18 years of age at the time of signing of the informed consent.
2. Diagnosis of HS based on clinical history and physical examination for at least 6 months prior to the Baseline visit.
3. Participants with moderate to severe HS defined as:

* A total of at least 5 AN count (abscesses and/or inflammatory nodules) AND
* Inflammatory lesions should affect at least 2 distinct anatomic areas (e.g., left and right axillae)

Key Exclusion Criteria:

1. Presence of more than 20 fistulae/tunnels (both draining and non-draining) in total at baseline.
2. Any active skin disease or conditions that may interfere with the assessment of HS.
3. Previous exposure to remibrutinib or other BTK inhibitors.
4. Use of other investigational drugs within 5 half-lives of enrollment, or within 30 days (for small molecules) prior to randomization, or until the pharmacodynamic effect has returned to baseline (for biologics), whichever is longer.
5. Significant bleeding risk or coagulation disorders.
6. History of gastrointestinal bleeding.
7. Requirement for anti-platelet (except for acetylsalicylic acid up to 100 mg/d or clopidogrel up to 75 mg/d) or anti-coagulant medication.

8. History or current hepatic disease.
9. Evidence of clinically significant cardiovascular, neurological, psychiatric, pulmonary, renal, hepatic, endocrine, metabolic, hematological disorders, gastrointestinal disease or immunodeficiency that, in the Investigator's opinion, would compromise the safety of the participant, interfere with the interpretation of the study results or otherwise preclude participation or protocol adherence of the participant.
10. History of hypersensitivity to any of the study drug constituents.
11. Known or suspected infectious disease that is active, chronic or recurrent which precludes the participant from participating in the trial as per investigator's assessment. These infectious diseases include and are not limited to opportunistic infections (e.g., tuberculosis, atypical mycobacterioses, listeriosis or aspergillosis) and/or known or suspected Human Immunodeficiency Virus (HIV) infection. Should it be required by local regulations and/or considered appropriate by the investigator, an HIV test can be performed to confirm eligibility.
12. History of live attenuated vaccine administration within 6 weeks prior to randomization or requirement to receive these vaccinations at any time while on study treatment.
13. Major surgery within 8 weeks prior to screening or planned surgery for the duration of the study.

Other protocol-defined inclusion/exclusion criteria may apply.

Canada

Novartis Investigative Site

Recruiting

Quebec,J1g 1x9,Canada

United States

Endeavor Health

Recruiting

Glenview,Illinois,60077,United States

Shannon Ewing

Laura Matias-Gomez

Email: lmatiasgomez@northshore.org

Complexions Dermatology

Recruiting

Danville,Virginia,24541,United States

Janaya Patron

Email: janaya.patron@careaccess.com

Keith Robinson

Austin Inst for Clinical Research

Recruiting

Pflugerville,Texas,78660,United States

Jenna McMinn

Phone: 512-259-2545
Email: jmcminn@atxresearch.com

Edward Lain

Rivergate Dermatology and Skin Care Center

Recruiting

Goodlettsville,Tennessee,37072-2301,United States

Keith H Loven

Mary Smith

Phone: 615-859-0900
Email: mary.smith@objective.health

Southern IN Clinical Trials

Recruiting

New Albany,Indiana,47150,United States

Megan Landis

Misty Humphress

Email: mhumphress@soinct.com

Total Skin and Beauty Dermatology Center PC

Recruiting

Birmingham,Alabama,35205,United States

Andria Thigpen

Email: andriat@totalskinandbeauty.com

Rajini Murthy

Accurate Clinical Research

Recruiting

Humble,Texas,77346,United States

Chinelo Fangtang

Rebecca Olivo

Email: rolivo@accurateclinicalresearch.com

Skin Specialists PC

Recruiting

Omaha,Nebraska,68144,United States

Joel Schlessinger

Samantha Jo Johnson

Phone: 402-334-7546
Email: sam.johnson@lovelyskin.com

Ctr for Dermatology Clinical Res

Recruiting

Fremont,California,95438,United States

Natalya Likhareva

Phone: 510-797-0140
Email: natalyal@ctr4derm.com

Sunil Dhawan

Care Access Alexandria

Recruiting

Arlington,Virginia,22206,United States

David Bray

Greneisha Jackson

Email: g.jackson@careaccess.com

Optima Dermatology Research

Recruiting

Boardman,Ohio,44512,United States

Hannah Titus

Email: htitus@optimatrials.com

Patrick Shannon

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/nct06840392*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06840392
2. #trial-eligibility
3. mailto:lmatiasgomez@northshore.org
4. mailto:janaya.patron@careaccess.com
5. tel:512-259-2545
6. mailto:jmcminn@atxresearch.com
7. tel:615-859-0900
8. mailto:mary.smith@objective.health
9. mailto:mhumphress@soinct.com
10. mailto:andriat@totalskinandbeauty.com
11. mailto:rolivo@accurateclinicalresearch.com
12. tel:402-334-7546
13. mailto:sam.johnson@lovelyskin.com
14. tel:510-797-0140
15. mailto:natalyal@ctr4derm.com
16. mailto:g.jackson@careaccess.com
17. mailto:htitus@optimatrials.com
18. tel:+41613241111
19. mailto:novartis.email@novartis.com
20. tel:1-888-669-6682
21. mailto:novartis.email@novartis.com