A Phase 3 Study to Assess Efficacy Safety and Tolerability of Remibrutinib in Adult Patients With Moderate to Severe Hidradenitis Suppurativa

Last Update: May 06, 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:
NCT06799000
Novartis Reference Number:CLOU064J12301
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
Jan 31, 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.

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