Phase 3b Study to Assess the Efficacy, Safety, and Tolerability of Remibrutinib in Comparison to Placebo, With Omalizumab as Active Control, in Adult CSU Patients, Followed by an Open-label 52-week Optional Extension.

Last Update: Mar 30, 2025

A Global, Multicenter, Randomized, Double-blind, Double-dummy, Parallel-group, Phase 3b Study to Assess the Efficacy, Safety, and Tolerability of Remibrutinib 25 mg b.i.d. in Comparison to Placebo With Omalizumab 300 mg Every 4 Weeks as Active Control Over 52 Weeks in Adult Patients With Chronic Spontaneous Urticaria Inadequately Controlled by Second Generation H1-antihistamines and an Open-label 52-week Optional Extension to Assess Long-term Efficacy, Safety and Tolerability of Remibrutinib 25 mg b.i.d.

ClinicalTrials.gov Identifier:
NCT06042478

Novartis Reference Number:CLOU064A2304

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 the core phase of the trial is to assess the efficacy, safety and tolerability of remibrutinib (LOU064) 25 milligrams (mg) twice a day (b.i.d.) over placebo for 24 weeks and in comparison to omalizumab 300 mg every 4 weeks (q4w) for 52 weeks in participants with chronic spontaneous urticaria (CSU) inadequately controlled by H1-antihistamines (H1-AH).

The purpose of the open-label extension phase is to assess efficacy, safety and tolerability up to two years for patients treated with remibrutinib and patients transitioned from omalizumab to remibrutinib at Week 52. In the extension phase, treatment will be with remibrutinib only (i.e., no background therapy). The extension phase will also fulfill the Novartis commitment to provide post-trial access to participants of the previous core phase. The study consists of 4 periods, and the total study duration is up to 112 weeks. Approximately 468 adult participants with CSU are expected to be randomized in the study.

Screening period: A screening period of up to 4 weeks will allow for the assessment of eligibility, determination of baseline disease activity and wash-out of prohibited medications.

Core Phase Treatment Period (52 weeks):

The treatment period will be double-dummy and double-blind, with placebo injections matching omalizumab 300 mg s.c. given to participants in the remibrutinib arm and placebo tablets matching remibrutinib 25 mg given to participants in the omalizumab arm (double-dummy). At the randomization visit, eligible participants

will be randomized to one of four treatment arms.

Extension Phase Treatment Period (52 weeks): Optional open-label extension where patients receive treatment with open-label remibrutinib 25 mg, for 52 weeks.

Follow-up period:

For patients that do not enter the extension phase, there will be a 16-week, treatment-free, safety follow-up period.

Patients that enter extension phase will have a 4-week treatment-free safety follow-up period at the end of the extension phase.

All participants will be on a stable, local label-approved standard dose of a second-generation H1-AH ("background therapy") throughout the entire core phase (starting a minimum of 7 days prior to randomization until the end of the core phase).

In addition, to treat unbearable symptoms of CSU flare-ups, participants will be allowed to use a different second-generation H1-AH on an as-needed basis ("rescue therapy").

Condition
Chronic Spontaneous Urticaria
Phase
Phase3
Overall Status
Recruiting
Number of Participants
468
Start Date
Nov 15, 2023
Completion Date
Jun 25, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Omalizumab

Active comparator
Drug

Placebo to omalizumab

Placebo followed by active comparator
Drug

Placebo to remibrutinib

Placebo followed by active treatment
Drug

Remibrutinib

Active treatment

Eligibility Criteria

Inclusion Criteria:

* Male and female adult participants ≥18 years of age at the time of signing the informed consent.
* CSU duration for ≥ 6 months prior to screening.
* Diagnosis of CSU inadequately controlled by second generation H1-AH at the time of randomization, defined as:
* The presence of itch and hives for ≥6 consecutive weeks prior to screening, despite the use of second-generation H1-AH during this time period.
* UAS7 score (range 0-42) ≥16, ISS7 score (range 0-21) ≥ 6 and HSS7 score (range 0- 21) ≥ 6 during the 7 days prior to randomization (Day 1).
* Documentation of hives within three months before randomization.
* Willing and able to complete an Urticaria Patient Daily Diary (UPDD) for the duration of the study and adhere to the study protocol.
* Participants must not have had more than one missing UPDD entry (either morning or evening) in the 7 days prior to randomization (Day 1).

Exclusion Criteria:

* Prior exposure to ligelizumab, omalizumab and other biologics with any effect in CSU, including anti-IgE therapies.
* Significant bleeding risk or coagulation disorders.
* History of gastrointestinal bleeding.
* Requirement for anti-platelet or anti-coagulant medication.
* History or current hepatic disease.
* 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.
* Evidence of helminthic parasitic infection as evidenced by stools being positive for a pathogenic organism according to local guidelines.
* Documented history of anaphylaxis.
* Pregnant or nursing (lactating) women.

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