

# **A Study to Investigate Efficacy, Safety, and Tolerability of Remibrutinib Compared With Placebo in Adults With CINDU Inadequately Controlled by H1-antihistamines**

Last Update: Mar 30, 2025

A 52-week Multi-center, Randomized, Double-blind, Placebo Controlled, Basket Study With an Open-label Extension to Investigate the Efficacy, Safety, and Tolerability of Remibrutinib (LOU064) in Chronic Inducible Urticaria (CINDU) in Adults Inadequately Controlled by H1-antihistamines

ClinicalTrials.gov Identifier:

[NCT05976243](#)

Novartis Reference Number: CLOU064M12301

[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**

This is a Phase 3, parallel group, placebo-controlled, double-blind, confirmatory study in patients with CINDU, with an optional Open-label Extension (OLE).

The purpose of the core period (52 weeks of treatment) of this study is to evaluate the efficacy, safety, and tolerability of remibrutinib (LOU064) vs. placebo in adults suffering from CINDU inadequately controlled by H1-antihistamines (H1-AHs).

The purpose of the OLE period is to collect long-term efficacy, safety, and tolerability data on remibrutinib in participants after having completed the Core period. This study consists of a core and extension periods.

The Core period (6 arms) has a total duration of up to 60 weeks including a double-blind placebo-controlled treatment period until Week 24 followed by open-label treatment with remibrutinib up to Week 52. The primary endpoint for all CINDU subtypes is assessed at Week 12.

The Core period consists of:

- \* Screening period (up to 4 weeks): During the screening period, participants who have provided informed consent will be assessed for study eligibility.

- \* Double-blind, placebo-controlled treatment period (24 weeks): 24 weeks of double-blind treatment with remibrutinib or placebo.

- \* Open-label treatment period (28 weeks): 28 weeks of open-label treatment with remibrutinib.

- \* Follow-up period: 4 weeks of treatment free follow-up. The open-label extension period consists of observation and treatment period. At the end of the core period of the study, if participants continue to experience symptoms, they will transition to the treatment period in OLE. If they do not experience symptoms

they will transition to the observation period in the OLE.

The duration of the Open-label Extension period will be approximately 3 years where participants can switch from observation to treatment depending on if they start developing symptoms. Only those participants participating in the Open-label Extension Treatment period will receive remibrutinib. The participants in the Open-label Extension Observation period will not receive remibrutinib

Condition

Chronic Inducible Urticaria

Phase

Phase3

Overall Status

Recruiting

Number of Participants

348

Start Date

Dec 07, 2023

Completion Date

Dec 31, 2028

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

## Interventions

Other

### Placebo

Placebo treated groups and arms

Drug

### Remibrutinib

Remibrutinib treated groups and arms

## Eligibility Criteria

Inclusion Criteria for core period:

1. Male and female participants  $\geq 18$  years of age at the time of signing of the ICFs
2. Confirmed CINDU diagnosis (as per guidelines) for symptomatic dermographism, cold urticaria or cholinergic urticaria for  $\geq 4$  months (defined as onset of CINDU with supporting documentation (e.g medical record, clinical history, photographs)) and inadequate control with H1-AH at local label approved doses at the time of randomization
3. The following response to the provocation test for each subtype is required at the randomization visit :

\* Symptomatic Dermographism: A Total Fric Score of  $\geq 3$  using the FricTest® 4.0 and a numerical rating scale score of  $\geq 5$  for itch after the provocation test.

\* Cold Urticaria: A Critical Threshold Temperature of  $\geq 15^{\circ}\text{C}$  using the TempTest® 4.0 and a numerical rating scale score of  $\geq 5$  for itch after the provocation test.

\* Cholinergic Urticaria: A physician global assessment of severity of hives  $\geq 2$  using the Pulse-controlled ergometry test and a numerical rating scale score of  $\geq 5$  for itch after the provocation test.

4. Cold Urticaria: Positive ice-cube test resulting in hives at the provocation site for participants at Screening.

5. Cholinergic urticaria: Participants must show sweating in performing the pulse-controlled ergometry test on day of randomization. Participants with anhidrosis must not be included.

Inclusion criteria for the OLE:

1. Participants who have completed the Core period up to Week 52 and are willing to enter the OLE period

Exclusion Criteria for core period:

\* 1. Previous use of remibrutinib or other BTK inhibitors.

2. Participants who have concomitant CSU at screening. Participants with resolved CSU at the time of screening can be included in the study.

3. Participants who have a familial form (e.g familial cold autoinflammatory syndrome, familial cold urticaria) of the target CINDU that is being considered for the participant's inclusion in this study.

4. Participants having a more defined other form of inducible urticaria than the target CINDU that is being considered for the participant's inclusion in this study.

5. Diseases, other than chronic inducible urticaria, with urticaria or angioedema symptoms including but not limited to urticarial vasculitis, erythema multiforme, cutaneous mastocytosis (urticaria pigmentosa) and hereditary or acquired angioedema

6. Any other skin disease associated with chronic itching that might influence, in the investigator's opinion, the study evaluations and results (e.g., atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.) or skin diseases associated with only wheals and no itch e.g asymptomatic dermographism

There are no exclusion criteria for OLE

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