

# Study of Remibrutinib (LOU064) Efficacy and Safety and Exploration of Its Mechanism of Action in Participants With Chronic Urticaria

NCT06865651

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Status	RECRUITING
Phase	Phase 2
Sponsor	Novartis Pharmaceuticals
Enrollment	44 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Signed informed consent must be obtained prior to participation in the study.
- Male and female participants e 18 years of age at the time of signing of the informed consent forms.
- CINDU patients: Confirmed diagnosis of CINDU with a duration of e 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. The response to the provocation test for each CINDU subtype is required before randomization (either during screening or prior to randomization on Day 1):
- CINDU patients: Patients should be symptomatic for their most bothersome symptom as assessed with the USDD during baseline with a NRS score of 3 or more
- CSU patients: Diagnosis of CSU (acc. to Zuberbier et al 2022c) not adequately controlled with H1-AH at approved doses alone for at least 4 weeks prior to randomization, as defined by all of the following:  
... and 3 more (see full listing online)

### Exclusion (43)

- Participants who have a familial/hereditary 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.
- Diseases, other than CSU or CINDU, with urticaria or angioedema symptoms including but not limited to:
- urticarial vasculitis, erythema multiforme, cutaneous mastocytosis (urticaria pigmentosa),
- food allergies yielding urticaria symptoms when the allergen is not avoided by the dietary habits of the participant
- hereditary or acquired angioedema.  
... and 38 more (see full listing online)

## Locations (17 total)

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Ziaderm Research LLC, North Miami Beach, Florida, United States  
Endeavor Health, Glenview, Illinois, United States  
Novartis Investigative Site, Grenoble, France  
... and 14 more locations

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<https://clinicaltrials.gov/study/NCT06865651>

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