24 Weeks Double-blind Randomized Placebo-controlled Trial to Evaluate Efficacy, PK, Safety of LOU064 in Adolescents (12 - <18) With CSU and Inadequate Response to H1-antihistamine Followed by Optional 3 Years Open-label Extension and an Optional 3 Ye...

Last Update: Apr 11, 2025
A Double-blind, Randomized, Placebo-controlled Trial to Evaluate the Efficacy, Pharmacokinetics and Safety of Remibrutinib (LOU064) for 24 Weeks in Adolescents From 12 to Less Than 18 Years of Age With Chronic Spontaneous Urticaria Inadequately Controlled by H1-antihistamines Followed by an Optional Open-label Extension for up to Another 3 Years and an Optional Safety Long-term Treatment-free Follow-up Period for up to an Additional 3 Years
ClinicalTrials.gov Identifier:
NCT05677451
Novartis Reference Number:CLOU064F12301
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 trial is:

1. to assess the efficacy, pharmacokinetics, and safety of remibrutinib vs. placebo in adolescents from 12 to \< 18 years of age suffering from chronic spontaneous urticaria inadequately controlled by H1-antihistamines
2. to collect long-term efficacy, safety and tolerability data on remibrutinib in adolescents after having completed 24 weeks of treatment
3. to collect safety data in this population for up to three years after the last dose of study treatment This trial consists of 3 different periods:

1. the "core period", which is randomized and double-blind, during which 2/3 participants will receive remibrutinib and 1/3 will receive placebo for 24 weeks. Total duration: approximately 32 weeks (10 site visits).
2. an optional "open-label extension (OLE) period" proposed to all participants who completed 24 weeks of treatment of the "core period" and all scheduled assessments planned at week 24 visit . Depending on their CSU symptoms (as assessed by the doctor), participants will either receive remibrutinib for 24 weeks, or enter an observational treatment-free period for 1 year. If the CSU symptoms return during the observational period, the participants can switch to the treatment period at any time (decided by the doctor). At the end of the 24-week treatment period, if CSU is controlled, participants will enter the 1-year observational period, otherwise, they can continue with another cycle of 24-week remibrutinib treatment. The number of remibrutinib treatment

or observational cycles will be limited to 6 times each. Total duration: from 1 year to approximately 3 years, and number of visits: from 3 to 15 (depending on the CSU symptoms).
3. an optional "long-term treatment-free follow-up period" proposed to all participants who completed at least 4 months treatment in the "OLE period". No treatment will be given. Duration: 3 years with 1 site visit and up to 4 phone call follow-up visits.

The primary clinical question of interest is what is the effect of remibrutinib treatment versus placebo on the change from baseline in UAS7, ISS7 and HSS7 scores after 12 weeks of treatment

Condition
Chronic Spontaneous Urticaria
Phase
Phase3
Overall Status
Recruiting
Number of Participants
100
Start Date
Jul 11, 2023
Completion Date
Mar 30, 2032
Gender
All
Age(s)
12 Years - 17 Years (Child)

Interventions

Drug

LOU064 (blinded)

LOU064 (blinded) active treatment
Drug

placebo

matching active drug

Eligibility Criteria

Key Inclusion Criteria:

* Male and female adolescent participants aged \>= 12 to \< 18 years of age at the time of signing the informed consent
* CSU duration for \>= 6 months prior to screening (defined as the onset of CSU determined by the investigator based on all available supporting documentation)
* 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 according to local treatment guidelines
* 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 (either at screening and/or at randomization; or documented in the participants' medical history)

Key Exclusion criteria:

* Previous use of remibrutinib or other BTK inhibitors
* Significant bleeding risk or coagulation disorders
* History of gastrointestinal bleeding
* Requirement for anti-platelet medication, except for acetylsalicylic acid up to 100 mg/d or clopidogrel up to 75 mg/d. The use of dual anti-platelet therapy (e.g., acetylsalicylic acid + clopidogrel) is prohibited
* 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
* History of hypersensitivity to any of the study drugs or its excipients or to drugs of similar chemical classes
* Participants having a clearly defined predominant or sole trigger of their chronic urticaria (chronic inducible urticaria) including urticaria factitia (symptomatic dermographism), cold-, heat-, solar-, pressure-, delayed pressure-, aquagenic-, cholinergic-, or contact-urticaria
* Other diseases with symptoms of urticaria or angioedema, including but not limited to urticaria vasculitis, urticaria pigmentosa, erythema multiforme, mastocytosis, hereditary angioedema, or drug-induced urticaria
* 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 or psoriasis

Other protocol-defined inclusion/exclusion criteria may apply.

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