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 Years Safety Long-term Treatment-free Follow-up

NCT05677451

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (6)

- 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 e 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)

... and 1 more (see full listing online)

Exclusion (10)

- 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

... and 5 more (see full listing online)

Locations (63 total)

Kern Research, Bakersfield, California, United States
Allergy and Asthma Medical Group and Research Center, San Diego, California, United States
Pediatric Dermatology of Miami at the Pediatric CoE, Coral Gables, Florida, United States
... and 60 more locations