

A Study to Evaluate Efficacy of Remibrutinib Compared to Dupilumab at Early Timepoints in Adults With Chronic Spontaneous Urticaria Inadequately Controlled by Second Generation H1-antihistamines

NCT06868212

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (10)

- Adults e 18 years of age at the time of signing the informed consent
- CSU duration for e 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 sgH1-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 sgH1-AH during the 7 days prior to randomization (Day 1):
- UAS7 score (range, 0-42) e 16, and
- ... and 5 more (see full listing online)

Exclusion (8)

- Previous use of remibrutinib or other bruton's tyrosine kinase (BTK) inhibitors
- Previous use of dupilumab
- Evidence of clinically significant cardiovascular (such as but not limited to myocardial infarction, unstable ischemic heart disease, NYHA Class III/IV left ventricular failure, arrhythmia and uncontrolled hypertension within 12 months prior to Visit 1), neurological, psychiatric, pulmonary, renal, hepatic (past history or current), endocrine or metabolic disorder, 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 hematological disorders (including coagulation disorders or significant bleeding risk)
- History or evidence of gastrointestinal disease (including gastrointestinal bleeding, e.g., in association with use of nonsteroidal anti-inflammatory drugs (NSAID), that was clinically relevant (e.g., where intervention was indicated or requiring hospitalization or blood transfusion)
- ... and 3 more (see full listing online)

Locations (114 total)

Allervie Clinical Research, Birmingham, Alabama, United States
Cahaba Derm and skin hlth ctr 27, Birmingham, Alabama, United States
Research Solutions of Arizona, Litchfield Park, Arizona, United States
... and 111 more locations

<https://clinicaltrials.gov/study/NCT06868212>

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