WHO CAN JOIN THE STUDY?

- Adults older than **18 years**
- Diagnosed with **chronic spontaneous urticaria (CSU)**
  Hives, itch and/or angioedema (e.g., face, lip swelling) for ≥6 weeks
- **Experiencing symptoms** despite treatment with current **second-generation antihistamine** therapy (i.e. Zyrtec or Claritin)
- Experiencing CSU symptoms longer than **6 months**
- Additional entry criteria will be assessed by the study doctor

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Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, health care professionals, and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

DO YOU HAVE QUESTIONS ABOUT THE STUDY?

Dr. Gary Gross
Pharmaceutical Research & Consulting

214-361-5555 or
rebecca.lindsey@daac-prc.com

Learn more about us

ITCH & HIVES
for 6 weeks or more?

Discover Our Chronic Spontaneous Urticaria (CSU) Research

The ReClaim Study
Study Code: CLDU064AUS02

A study to compare remibrutinib to dupilumab at early timepoints in adults with CSU who remain symptomatic despite treatment with second-generation H1-antihistamines (i.e. Zyrtec, Claritin)

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WHAT IS CSU?

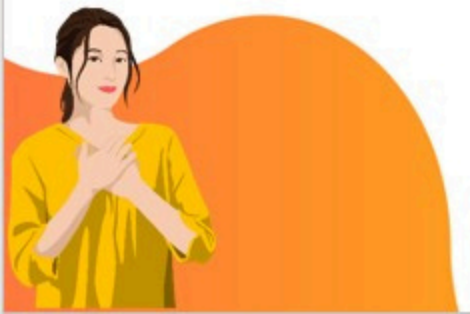
- Itchy hives (wheals) and/or swelling lasting longer than 6 weeks
- Hives are unpredictable or have no known external cause
- Caused by immune system imbalance

Living with CSU

Constant itching, unpredictable hives that often require healthcare visits can make work, school, family and social life difficult or stressful for those affected by CSU

Study Purpose

Evaluate the efficacy (effect) of remibrutinib compared to dupilumab at early timepoints in adults with CSU who remain symptomatic despite drugs called second-generation H1-antihistamines (i.e. Zyrtec, Claritin)



REMIBRUTINIB AND DUPILUMAB

Remibrutinib is a new pill we are studying that inhibits an enzyme called **Bruton's tyrosine kinase (BTK).**
When active, BTK can cause inflammation resulting in CSU symptoms (itch and hives). This treatment may lower the activity of these cells.

Dupilumab is a monoclonal antibody that inhibits proteins called "**interleukin (IL)-4 and IL-13.**" These proteins are involved in inflammation in conditions like CSU.

Possible benefits

In 2 completed CSU clinical studies, **remibrutinib quickly and continuously improved itch and hives** in patients who continued to have symptoms that were not controlled by medications like Zyrtec or Claritin.

Dupilumab is an approved medication that showed benefit in patients with CSU.

Possible side effects

Remibrutinib

- Potential risks include: Infection, minor bleeding or bruising under the skin, reduced blood cell count (hemoglobin, platelets, neutrophils)

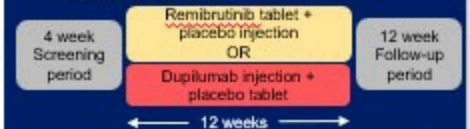
Dupilumab

- Potential risks include: Injection-site reactions, conjunctivitis (pink-eye), eye irritation, throat irritation, cold sores

Metz M, Giménez-Arnau A, Hide M, et al. Remibrutinib in Chronic Spontaneous Urticaria. N Engl J Med. 2025;392:984-94. DOI: 10.1056/NEJMoa2408792.

STUDY DESIGN

- You will participate in the study for up to 28 weeks, attending up to 8 visits at the study site (approximately every 2 weeks)
- The study is randomized, meaning you will be assigned to receive either remibrutinib or dupilumab
- The study is blinded, so neither you nor the study doctor will know which treatment you receive. You will get a placebo that will either be a pill or an injection. A placebo is an inactive substance that contains no medicine.



- During visits, procedures will include a physical exam, vital signs check, blood and urine sample collection, and an electrocardiogram (looks at the activity of your heart).
- After completing the 12-week blinded treatment period, you may either enter a 12-week follow-up period OR you may join a 12-week extension study to receive remibrutinib if your Study Doctor thinks you may benefit and it is not commercially available (via prescription).
- Reimbursement for travel may be available to support your participation in the trial.
- While you may not benefit directly from this study, it could help other patients.
- Your participation is appreciated but entirely voluntary, and you may leave the study at any time. Thank you for considering this study.