Remibrutinib in Real-world Clinical Practice - a US Sub-study

NCT07358780

Status	RECRUITING
Sponsor	Novartis Pharmaceuticals
Enrollment	505 participants

Key Eligibility Criteria

Inclusion (7)

- Patients with a confirmed diagnosis of primary CSU by the treating physician.
- Aged at least 18 years on the date of enrolment.
- Written informed consent of the patient to participate in the study (according to country specifications) and willingness to complete full follow-up period of 24 months.
- Cohort 1: Inadequate control of CSU despite licensed dose of sgH1-AH (no other pre-treatments permitted) and decision (independent of study enrolment) to escalate sgH1-AH treatment.
- Cohort 2: Inadequate control of CSU despite licensed dose or escalated sgH1-AH(s) (no other pre-treatment with exception of first generation H1-AH permitted) with decision (independent of study enrolment) to switch to remibrutinib treatment as per local label.

... and 2 more (see full listing online)

Exclusion (5)

- Currently enrolled in a clinical trial or on any experimental treatment.
- Patients within the safety follow-up phase of a previous interventional or non-interventional study.
- Patients who received remibrutinib as an investigational medical product during a remibrutinib interventional study or MAP/PSDS at any time in the past.
- Patients not capable or willing to continuously provide ePRO/eDiary data via electronic means throughout the duration of the study.
- Patients who are treated with remibrutinib outside of the local label.

Locations (1 total)

Cleaver Dermatology, Kirksville, Missouri, United States