ForPatients
by Roche

Infectious Diseases

A study of long-term effects of fenebrutinib treatment in patients with chronic spontaneous urticaria

A Study to Evaluate the Long-term Safety and Efficacy of Fenebrutinib in Participants Previously Enrolled in a Fenebrutinib Chronic Spontaneous Urticaria (CSU) Study

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT03693625 2018-002296-17 GS40868

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II Open-Label Extension Study To Evaluate The Long-Term Safety And Efficacy Of Fenebrutinib In Patients Previously Enrolled In A Fenebrutinib Chronic Spontaneous Urticaria Study

Trial Summary:

This is a Phase II, multicenter, open-label extension (OLE) study to evaluate the long-term safety and efficacy of fenebrutinib in participants with Chronic Spontaneous Urticaria (CSU) who have completed the treatment period in a fenebrutinib CSU parent study. Participants may enroll in this OLE study at any time after completing the treatment period of the parent study. Participants will receive open-label fenebrutinib at a dose of 200 milligram (mg) orally twice a day. Treatment may continue until the end of the study.

Genentech, Inc.	Phase 2
Sponsor	Phase

NCT03693625 2018-002296-17 GS40868
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 75 Years	No

This clinical trial was done to study a new medicine called, “fenebrutinib”, for the treatment of patients with “chronic spontaneous urticaria” or “CSU”. This study was done to find out if the long-term use of fenebrutinib was safe for patients with CSU. Researchers also wanted

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to find out whether fenebrutinib could provide improvements to CSU symptoms in patients when used long-term. Thirty-one patients took part in this study at nine study centers in the USA.

Inclusion Criteria:

- Ability to comply with the study protocol, in the investigator's judgment
- Completion of the treatment period as specified in the parent study
- Acceptable demonstration of tolerance to study drug during the parent study as determined by the investigator or Medical Monitor
- For participants receiving treatment with proton-pump inhibitors (PPIs) or H2-receptor antagonists (H2RAs), agreement to maintain treatment at a stable dose for the first 12 weeks of the study
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 4 weeks after the final dose of fenebrutinib
- Treatment with any investigational agent or live/attenuated vaccine in the preceding 6 weeks
- Any signs or symptoms of infection judged by the investigator to be clinically significant since completing the treatment period of the parent study
- Any significant changes (e.g., events, changes in medication) occurring after completion of participation in the parent study that, in the investigator's judgment, would increase the risk of adverse events in this OLE study

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