ForPatients
by Roche

Infectious Diseases

A study to compare different doses of fenebrutinib with a “placebo” – in patients with an autoimmune disease called “chronic spontaneous urticaria”

Efficacy and Safety of GDC-0853 in Participants With Refractory Chronic Spontaneous Urticaria (CSU)

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03137069 2016-004624-35 GS39684

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, Multicenter, Randomized, Double-Blind, Placebo-Controlled Pilot and Dose-Ranging Study of GDC-0853 in Patients With Refractory Chronic Spontaneous Urticaria (CSU).

Trial Summary:

The purpose of this study is to evaluate the efficacy, safety and pharmacokinetics of GDC-0853 compared with placebo in participants with Refractory Chronic Spontaneous Urticaria (CSU) already treated with anti-histamines. Participants have the option to enter the Open-Label Extension (OLE) study after completing the 8-week treatment period.

Genentech, Inc.	Phase 2
Sponsor	Phase

NCT03137069 2016-004624-35 GS39684
Trial Identifiers

Eligibility Criteria:

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

Fenebrutinib is a study medicine intended for the treatment of patients with “autoimmune diseases”. Researchers wanted to find out if fenebrutinib was effective in patients with chronic spontaneous urticaria (CSU) – an autoimmune disease. This was a double-blind

study where patients and researchers did not know which treatment group each patient belonged to. Some patients got fenebrutinib and others got a placebo (no medicine). This way, the effect of fenebrutinib could be compared against the placebo (no medicine).

Inclusion Criteria:

- Aged 18-75 years, inclusive
- Diagnosis of chronic spontaneous urticaria (CSU) refractory to H1 antihistamines at the time of randomization
- Willing and able to complete an Urticaria Participant Daily eDiary for the duration of the study
- No evidence of active or latent or inadequately treated infection with tuberculosis (TB)
- Partcipants with a history of Bacille Calmette-Guérin (BCG) vaccination should be screened using the QuantiFERON-TB-Gold (QFT) test
- Only for participants currently receiving proton-pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs): Treatment must be at a stable dose during the 2-week screening period prior to randomization and with a plan to remain at a stable dose for the duration of the study
- For women of childbearing potential: Agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 4 weeks after the last dose of study drug. Women must refrain from donating eggs during this same period.

Exclusion Criteria:

- Treatment with omalizumab or other monoclonal antibody therapies used to treat CSU within 4 months prior to screening or primary nonresponse to omalizumab
- Use of a non-biologic investigational drug or participation in an investigational study with a non-biologic drug within 30 days prior to study drug administration on Day 1 (or within 5 half-lives of the investigational product, whichever is greater)
- Use of a biologic investigational therapy or participation in an investigational study involving biologic therapy within 90 days or 5 half-lives, whichever is greater, prior to study drug administration on Day 1
- Previous treatment with GDC-0853 or other Bruton's tyrosine kinase (BTK) inhibitors
- Participants whose urticaria is solely due to physical urticaria
- Other diseases with symptoms of urticaria or angioedema, including urticarial vasculitis, urticaria pigmentosa, erythema multiforme, mastocytosis, hereditary or acquired angioedema, lymphoma, or leukemia
- Atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, or other skin disease associated with itch such as psoriasis
- Routine doses of the following medications within 30 days prior to screening: systemic or cutaneous (topical) corticosteroids (prescription or over the counter), hydroxychloroquine, methotrexate, cyclosporine, or cyclophosphamide
- Prior utilization of intravenous (IV) steroids for treatment of laryngeal angioedema
- Intravenous immunoglobulin G (IV IG) or plasmapheresis within 30 days prior to screening
- History of anaphylactic shock without clearly identifiable avoidable antigen
- Hypersensitivity to GDC-0853 or any component of the formulation
- Major surgery within 8 weeks prior to screening or surgery planned prior to end of study (12 weeks after randomization)
- Require any prohibited concomitant medications
- History of live attenuated vaccine within 6 weeks prior to randomization or requirement to receive these vaccinations at any time during study drug treatment
- Evidence of clinically significant cardiac, neurologic, psychiatric, pulmonary, renal, hepatic, endocrine, metabolic, or gastrointestinal (GI) disease that, in the investigator's opinion, would compromise the

safety of the participant, interfere with the interpretation of the study results or otherwise preclude participant participation

- Current treatment with astemizole, terfenadine, and/or ebastine
- Uncontrolled disease states, such as asthma, psoriasis, or inflammatory bowel disease, where flares are commonly treated with oral or parenteral corticosteroids