

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
Completed

Trial Runs In
3 Countries

Trial Identifier
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.
Sponsor

Phase 2
Phase

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Eligibility Criteria:

Gender
All

Age
18 Years & # 75 Years

Healthy Volunteers
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)
- Participants 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

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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