ForPatients
by Roche

Systemic Lupus Erythematosus

A study to compare different doses of fenebrutinib with a “placebo” – in patients with lupus

Study of the Safety and Efficacy of GDC-0853 in Participants With Moderate to Severe Active Systemic Lupus Erythematosus

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT02908100 2016-001039-11 GA30044

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, Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of GDC-0853 in Patients With Moderate to Severe Active Systemic Lupus Erythematosus

Trial Summary:

This is a study to evaluate the safety and efficacy of GDC-0853 in combination with standard of care therapy in participants with moderate to severe active systemic lupus erythematosus (SLE).

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT02908100 2016-001039-11 GA30044
Trial Identifiers

Eligibility Criteria:

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

Researchers wanted to find out what effect, good or bad, fenebrutinib caused in comparison to a placebo, in patients with systemic lupus erythematosus (lupus). A computer randomly decided which patients joined one of two fenebrutinib dose groups and which patients joined the placebo group. This was a double-blind study where patients and researchers did not know which of the 3 groups each patient belonged to.

Inclusion Criteria:

- Fulfillment of SLE classification criteria according to either American College of Rheumatology (ACR) or Systemic Lupus International Collaborating Clinics (SLICC) criteria at any time prior to or at screening
- At least one serologic marker of SLE at screening as follows: positive antinuclear antibody (ANA) test by immunofluorescent assay with titer >/= 1:80; or positive anti-double-stranded DNA (anti-dsDNA) antibodies; or positive anti-Smith antibody
- At both screening and Day 1, moderate to severe active SLE, defined as meeting all of the following unless indicated otherwise: Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score # 8 (at screening only) with clinical SLEDAI-2K score >/= 4.0 (at both screening and Day 1), Physician's Global Assessment >/= 1.0 (out of 3), and currently receiving at least one standard oral treatment for SLE
- If on oral corticosteroids (OCS), the dose must be </= 40 mg/day prednisone (or equivalent)
- Stable doses of anti-malarial or immunosuppressive therapies
- Participants must be willing to avoid pregnancy

Exclusion Criteria:

- Proteinuria > 3.5 g/24 h or equivalent using urine protein-to-creatinine ratio (uPCR) in a first morning void urine sample
- Active proliferative lupus nephritis (as assessed by the investigator) or histological evidence of active Class III or Class IV lupus nephritis on renal biopsy performed in the 6 months prior to screening (or during the screening period)
- History of having required hemodialysis or high dose corticosteroids (>100 mg/d) prednisone or equivalent) for the management of lupus renal disease within 90 days of Day 1
- Neuropsychiatric or central nervous system lupus manifestations
- Serum creatinine > 2.5 mg/dL, or estimated glomerular-filtration rate < 30 milliliter per minute (mL/min) or on chronic renal replacement therapy
- History of receiving a solid organ transplant
- Evidence of active, latent, or inadequately treated infection with Mycobacterium tuberculosis (TB)
- Significant and uncontrolled medical disease within the 12 weeks prior to screening in any organ system (e.g., cardiac, neurologic, pulmonary, renal, hepatic, endocrine, metabolic, gastrointestinal, or psychiatric) not related to SLE, which, in the investigator's or Sponsor's opinion, would preclude study participation
- History of cancer, including hematological malignancy and solid tumors, within 10 years of screening
- Need for systemic anticoagulation with warfarin, other oral or injectable anticoagulants, or anti-platelet agents
- Evidence of chronic and/or active hepatitis B or C