ForPatients
by Roche

Autoimmune Disorder

A study of the long-term effects of fenebrutinib treatment in patients with lupus

An Extension Study of GDC-0853 in Participants With Moderate to Severe Active Systemic Lupus Erythematosus

Trial Status	Trial Runs In	Trial Identifier
Terminated	11 Countries	NCT03407482 2017-001764-37 GA30066

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 of Patients Previously Enrolled in Study GA30044 to Evaluate the Long-Term Safety and Efficacy of GDC-0853 in Patients With Moderate to Severe Active Systemic Lupus Erythematosus

Trial Summary:

This Phase II, multicenter, open-label extension (OLE) study will evaluate the long-term safety and efficacy of GDC-0853 in participants with systemic lupus erythematosus (SLE) who have completed Study GA30044 (NCT02908100) up to 48 weeks.

Genentech, Inc.	Phase 2
Sponsor	Phase

NCT03407482 2017-001764-37 GA30066
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 76 Years	No

This clinical trial was done to study a new medicine called, “fenebrutinib”, for the treatment of patients with “lupus”. Researchers wanted to know if fenebrutinib was safe over a long-term period when given to patients with lupus. One hundred and sixty patients took part in this study at 49 study centers in 11 countries.

Inclusion Criteria:

- Able to comply with the study protocol, in the investigator's judgment
- Completion of Study GA30044 up to 48 weeks
- Acceptable safety and tolerability during Study GA30044 as determined by the investigator

Exclusion Criteria:

- Met protocol-defined treatment-stopping criteria during Study GA30044
- An adverse event in Study GA30044 that required permanent discontinuation of study drug
- In the opinion of the investigator, any new, significant, uncontrolled comorbidity or new clinical manifestation (related to SLE or not) that requires medications not allowed in this protocol; or could put the participant at undue risk from a safety perspective
- Any uncontrolled or clinically significant laboratory abnormality that would affect safety, interpretation of study data, or the participant's participation in the study in the opinion of the investigator in consultation with the Medical Monitor