ForPatients
by Roche

Rheumatoid Arthritis

A study of long-term effects of fenebrutinib treatment in patients with rheumatoid arthritis

A Study to Evaluate the Long-Term Safety and Efficacy of GDC-0853 in Participants With Moderate to Severe Rheumatoid Arthritis Enrolled in Study GA29350 (NCT02833350)

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT02983227 2016-000498-19 GA30067

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 GA29350 to Evaluate the Long-Term Safety and Efficacy of GDC-0853 in Patients With Moderate to Severe Rheumatoid Arthritis

Trial Summary:

A study to evaluate the long-term safety and efficacy of GDC-0853 in participants with moderate to severe active Rheumatoid Arthritis (RA) who have completed 12 weeks of study treatment in Study GA29350. Eligible participants from Study GA29350 who elect to participate will receive treatment with GDC-0853 twice daily (BID) in an open-label fashion for 52 weeks, followed by a safety follow-up period of 8 weeks.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT02983227 2016-000498-19 GA30067
Trial Identifiers

Eligibility Criteria:

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

Researchers wanted to find out what effect, good or bad, fenebrutinib caused in patients with rheumatoid arthritis (RA) who received long-term treatment. This was an “open-label extension” study. Open-label meant that patients and researchers knew what treatment the patients were getting. It was an “extension study” because RA patients were

required to have previously participated in another study that investigated fenebrutinib (and placebo) for RA disease.

Inclusion Criteria:

- Completion of treatment as specified in Study GA29350, including completion of the Day 84 study visit assessments
- Acceptable safety and tolerability during Study GA29350 as determined by the investigator or Medical Monitor
- Have not received any prohibited medications in Study GA29350
- While taking methotrexate, must be willing to receive oral folic acid (at least 5 milligrams per week [mg/week])
- If receiving oral corticosteroids (less than or equal to [</=] 10 milligrams per day [mg/day] prednisone or equivalent) and/or non-steroidal anti-inflammatory drugs, doses have remained stable for the duration of Study GA29350

Exclusion Criteria:

- Met protocol defined treatment stopping criteria during Study GA29350
- Treatment with any investigational agent (i.e., other than study drug) or live/attenuated vaccine or any other prohibited medication during Study GA29350 or since the last administration of study drug in Study GA29350
- In the opinion of the investigator, any new (since initially enrolling in the Phase II Study GA29350), significant, uncontrolled comorbidity that would increase the risk to the participant in Study GA30067
- Pregnant or lactating, or intending to become pregnant during the study
- Participants who experienced a de novo or reactivated serious viral infection such as hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV) during the Phase II Study GA29350
- Any major episode of infection requiring hospitalization or treatment with intravenous antibiotics during the Phase II Study GA29350
- Participants who developed a malignancy during the Phase II Study GA29350
- 12-lead electrocardiogram (ECG) on Day 84 in Study GA29350 that demonstrates clinically relevant abnormalities that may affect participant safety or interpretation of study results
- Current treatment with medications that are well known to prolong the QT interval