ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)Chronic Lymphocytic Leukemia

A study to look at how safe was it to give people with blood cancer (non-Hodgkin's lymphoma and chronic lymphocytic leukemia) – different doses of a study medicine (fenebrutinib)

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT01991184 GO29089

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:

An Open-Label, Phase I, Dose-Escalation Study Evaluating The Safety And Tolerability Of Gdc-0853 In Patients With Relapsed Or Refractory B-Cell Non-Hodgkin's Lymphoma And Chronic Lymphocytic Leukemia

Trial Summary:

This clinical trial was done to study a new medicine (fenebrutinib) for the treatment of patients with blood cancer. This was a phase 1, dose-escalation study to find out which dose of fenebrutinib was safe and tolerable for people with B-cell non-Hodgkin's lymphoma (B-NHL) and chronic lymphocytic leukemia (B-CLL). Twenty-four people with B-NHL or B-CLL – that had come back (relapsed) or did not respond to medicine (refractory) – where the disease had gotten worse (progressed) even after getting available medicines – and for which no other effective medicine was available – took part in this study. The study took place at nine study centers in two countries – USA and Australia.

Genentech, Inc. (Part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

NCT01991184 GO29089
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

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- Age >/= 18 years
- ECOG score of 0-1
- One of the following histologically-documented hematologic malignancies for which no effective standard therapy exists: indolent non Hodgkin's lymphoma (NHL), follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), or chronic lymphocytic leukemia (CLL)
- At least one site of disease that, as seen on CT scan, is > 1.5 cm in the greatest transverse diameter or > 1.0 cm in short axis diameter (except for patients with CLL)
- An available tumor specimen
- Adequate hematologic and organ function
- For female patients of childbearing potential and male patients with partners of childbearing potential, use of effective contraceptive(s) as defined by protocol for the duration of the study

Exclusion Criteria:

- Life expectancy < 12 weeks
- < 3 weeks since the last anti-tumor therapy, including chemotherapy, biologic, experimental, hormonal or radiotherapy (with the exception of leuprolide or similar medications for prostate cancer)
- Recent major surgical procedure or traumatic injury, or unhealed incisions or wounds
- Active infection requiring IV antibiotics
- Clinically significant history of liver disease, including viral or other hepatitis, current alcohol abuse, or cirrhosis.
- Primary CNS malignancy or untreated/active CNS metastases (progressing or requiring anticonvulsants or corticosteroids for symptomatic control)
- History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin cancer, Stage I uterine cancer, or other cancers with a similar outcome
- Cardiovascular dysfunction, including ventricular dysrhythmias or risk factors for ventricular dysrhythmias
- Pregnancy, or lactation
- Any other diseases that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the patient at high risk from treatment complications

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