ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

Alectinib compared with chemotherapy in previously treated patients with ALK-positive NSCLC (ALUR)

Alectinib Versus Pemetrexed or Docetaxel in Anaplastic Lymphoma Kinase (ALK)-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) Participants Previously Treated With Platinum-Based Chemotherapy and Crizotinib

Trial Status	Trial Runs In	Trial Identifier
Completed	15 Countries	NCT02604342 2015-000634-29 MO29750

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:

Randomized, Multicenter, Phase III, Open-Label Study of Alectinib Versus Pemetrexed or Docetaxel in Anaplastic Lymphoma Kinase-Positive Advanced Non Small Cell Lung Cancer Patients Previously Treated With Platinum-Based Chemotherapy and Crizotinib

Trial Summary:

This randomized active-controlled multicenter Phase III open-label study will evaluate and compare between treatment groups the efficacy of alectinib versus chemotherapy in participants with ALK-positive advanced NSCLC who were previously treated with chemotherapy and crizotinib, as measured by investigator-assessed progression-free survival (PFS) and to evaluate and compare between treatment groups the central nervous system (CNS) objective response rate (C-ORR) in participants with measurable CNS metastases at baseline, as assessed by an Independent Review Committee (IRC).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02604342 2015-000634-29 MO29750
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) NSCLC that is ALK-positive. ALK positivity must have been determined by a validated fluorescence in situ hybridization (FISH) test (recommended probe, Vysis ALK Break-Apart Probe) or a validated immunohistochemistry (IHC) test (recommended antibody, clone D5F3)
- Participant had received two prior systemic lines of therapy, which must have included one line of platinum-based chemotherapy and one line of crizotinib
- Prior CNS or leptomeningeal metastases allowed if asymptomatic
- Participants with symptomatic CNS metastases for whom radiotherapy is not an option will be allowed to participate in this study
- Measurable disease by RECIST Version 1.1 prior to the administration of study treatment
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
- For all females of childbearing potential, a negative pregnancy test must be obtained within 3 days before starting study treatment

Exclusion Criteria:

- Participants with a previous malignancy within the past 3 years are excluded (other than curatively treated basal cell carcinoma of the skin, early gastrointestinal [GI] cancer by endoscopic resection or in situ carcinoma of the cervix)
- Participants who have received any previous ALK inhibitor other than crizotinib
- Any GI disorder that may affect absorption of oral medications