ForPatients
by Roche

NeoplasmsTumorCancer

A Roll Over Study of Alectinib in Patients With Anaplastic Lymphoma Kinase (ALK)-Positive or Rearranged During Transfection (RET)-Positive Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	9 Countries	NCT03194893 2017-000207-24 BO39694

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 Multicenter, International, Rollover Study of Alectinib in Patients With Anaplastic Lymphoma Kinase (ALK)-Positive or Rearranged During Transfection (RET)-Positive Cancer

Trial Summary:

The purpose of this study is to provide continued treatment with alectinib or crizotinib as applicable to participants with ALK- or RET positive cancer who were previously enrolled in any Roche-sponsored alectinib study and who are deriving continued clinical benefit from alectinib or crizotinib in the parent trial at the time of parent trial closure.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03194893 2017-000207-24 BO39694
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

Inclusion Criteria:

- Participants enrolled in a Roche-sponsored alectinib trial who are experiencing a clinical benefit from alectinib or crizotinib treatment at the time of discontinuation from the parent trial and for whom a switch to commercial supply is not feasible

- Collected study termination data, including efficacy and safety data, as required by the parent study on the electronic Case Report Form (eCRF)
- For women who are not postmenopausal (# 12 months of non-therapy-induced amenorrhea) or surgically sterile (absence of ovaries and/or uterus): agreement to remain abstinent or use single or combined contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 3 months after the last dose of study drug
- For men: agreement to remain abstinent or use a contraceptive method that results in a failure rate of < 1% per year during the treatment period and for at least 3 months after the last dose of study drug.

Exclusion Criteria:

- Evidence of lack of clinical benefit in parent trial during the screening phase of this rollover study
- Permanent discontinuation of alectinib or crizotinib for any reason during the parent study or before first dose of study drug in the rollover study
- Evidence of an adverse event for which the parent protocol stipulates permanent discontinuation
- Pregnant or breastfeeding women
- Ongoing serious adverse event that has not resolved to baseline level or Grade #1 prior to first dose of study treatment in the rollover study
- Treatment interruption for more than 21 days due to an adverse event since the last administration of alectinib or crizotinib in the parent trial. Any ongoing adverse events that require temporary treatment interruption must be resolved to baseline grade or assessed as stable and not requiring further treatment interruption by the investigator
- Administration of strong/potent cytochrome P450 (CYP) 3A inhibitors or inducers within 14 days prior to the first dose of treatment on this study and while on treatment with crizotinib
- Any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol requirements and/or follow-up procedures; these conditions should be discussed with the participant before trial entry