ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

A study to compare alectinib with chemotherapy in people with ALK-positive non-small cell lung cancer after surgery (ALINA)

A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus Adjuvant Platinum-Based Chemotherapy in Patients With Completely Resected Stage IB (Tumors Equal to or Larger Than 4cm) to Stage IIIA Anaplastic Lymphoma Kinase Positive Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	27 Countries	NCT03456076 2017-004331-37 BO40336

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 III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus Adjuvant Platinum-Based Chemotherapy in Patients With Completely Resected Stage IB (Tumors Equal to or Larger Than 4cm) to Stage IIIA Anaplastic Lymphoma Kinase Positive Non-Small Cell Lung Cancer

Trial Summary:

This randomized, active-controlled, multicenter, open-label, Phase III study is designed to investigate the efficacy and safety of alectinib compared with platinum-based in the adjuvant setting. Participants in the experimental arm will receive alectinib at 600 mg orally twice daily (BID) taken with food for 24 months. Participants in the control arm will receive one of the protocol specified platinum based chemotherapy regimens for 4 cycles. Following treatment completion, participants will be followed up for their disease until disease recurrence. At the time of disease recurrence, participants will enter a survival follow-up until death, withdrawal of consent or study closure, whichever occurs earlier.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03456076 2017-004331-37 BO40336
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**# 18 Years**	**No**

1. Why is this study needed?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. NSCLC usually develops in the tissues lining the lungs and can spread to nearby lymph nodes and other organs.

Surgery is the first treatment for people with NSCLC that can be removed. Treatment, such as chemotherapy, can be given after surgery to reduce the risk of cancer coming back. However, treatment may not always work for people with different types of NSCLC. So, better treatments are needed.

Targeted therapy is a type of treatment that treats abnormal cells (e.g. cancer cells) in the body. It causes less harm to normal cells. This means it may cause fewer unwanted effects than chemotherapy. *ALK*-positive lung cancer is a specific type of NSCLC. It is caused by a mutation in a section of DNA (a gene) in the body called *anaplastic lymphoma kinase*, or *ALK*. A mutation is a change in a gene that can be sudden or passed on from parents so that the gene is different from what is found in healthy cells. The mutated version of *ALK* makes a protein that causes lung cells to start growing and multiplying in an uncontrolled and abnormal way. ALK-targeting medicines may work better than chemotherapy to stop NSCLC coming back after surgery.

This study is testing a medicine called alectinib. It is being developed to stop *ALK*-positive NSCLC coming back after a person has had surgery to remove it. Alectinib is an experimental medicine. This means health authorities (like the European Medicines Agency) have not approved alectinib for the treatment of people with *ALK*-positive NSCLC after they have had surgery. Alectinib is approved in many countries for treating *ALK*-positive NSCLC that has spread in the body.

This study aims to compare the effects of alectinib with chemotherapy in people with *ALK*-positive NSCLC after they have had surgery.

2. Who can take part in the study?

People of at least 18 years of age with *ALK*-positive NSCLC can take part in the study if they have had surgery to completely remove the cancer 1 to 3 months before starting the study. They must also be able to be given platinum-based chemotherapy (medicine that contains platinum).

People may not be able to take part in this study if they have been given an ALK-targeting medicine before, they require radiotherapy treatment after their lung cancer surgery, or

if they have certain health problems, such as liver disease. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment.

Everyone in this study will join 1 of the 2 groups randomly (like flipping a coin) and be given either alectinib as a pill twice every day for 2 years OR standard chemotherapy, given as a drip into the vein every 3 weeks for 3 months. Participants will have an equal chance of being placed in either group.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit 1 month after completing the study treatment, during which the study doctor will check on the participant's wellbeing. If NSCLC comes back or they are diagnosed with a different type of NSCLC, participants will be asked to attend a clinic visit within 1 month. They will then receive follow-up telephone calls from the study doctor to check on their wellbeing every 6 months for as long as they agree to it. Total time of participation in the study could be more than 7 years depending on when they join the study. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main result measured in the study to assess if the medicine has worked is the time between no signs of NSCLC on scans or tests after surgery and the signs that it has come back.

Other key results measured in the study include:

- How long people live
- The number and seriousness of unwanted effects
- How alectinib gets to different parts of the body, and how the body changes alectinib and gets rid of it
- Questionnaire answers directly from the participant on how well they are doing, and how their health and treatment impact their daily life and their ability to function and enjoy life

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drugs Participants may have unwanted effects of the drugs used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Alectinib and platinum-based chemotherapy Participants will be told about the known unwanted effects of alectinib and platinum-based chemotherapy, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Known unwanted effects of alectinib include wanting to throw up, throwing up, a low number of red blood cells, tiredness, pain or discomfort in the head and muscle pain.

Known unwanted effects of platinum-based chemotherapy include throwing up, wanting to throw up, a low number of red blood cells, frequent watery stools and hair loss.

Platinum-based chemotherapy will be given as a drip into a vein. Known unwanted effects of a drip into a vein include throwing up, wanting to throw up, a feeling of coldness that makes the body shiver, low or high blood pressure, fever, pain or discomfort in the head, frequent watery stools, shortness of breath and cough .

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Age #18 years
- Complete resection of histologically confirmed Stage IB (tumor # 4 cm) to Stage IIIA (T2-3 N0, T1-3 N1, T1-3 N2, T4 N0-1) NSCLC as per Union Internationale Contre le Cancer / American Joint Committee on Cancer, 7th edition, with negative margins, at 4-12 weeks before enrollment
- If mediastinoscopy was not performed preoperatively, it is expected that, at a minimum, mediastinal lymph node systematic sampling will have occurred
- Documented ALK-positive disease according to an FDA-approved and CE-marked test
- Eligible to receive a platinum-based chemotherapy regimen according to the local labels or guidelines
- Eastern Cooperative Oncology Group Performance Status of Grade 0 or 1
- Adequate hematologic and renal function

- For women of childbearing potential: agreement to remain abstinent or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for at least 90 days after the last dose of alectinib or according to local labels or guidelines for chemotherapy
- For men: agreement to remain abstinent or use contraceptive measures, and agreement to refrain from donating sperm for at least 90 days after the last dose of alectinib or according to local labels or guidelines for chemotherapy. Men must refrain from donating sperm during this same period
- Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 90 days after the last dose of alectinib or according to local labels or guidelines for chemotherapy
- Prior adjuvant radiotherapy for NSCLC
- Prior exposure to systemic anti-cancer therapy and ALK inhibitors
- Stage IIIA N2 patients that, in the investigator's opinion, should receive post-operative radiotherapy treatment are excluded from the study
- Known sensitivity to any component of study drug to which the patient may be randomized. This includes, but is not limited to, patients with galactose intolerance, a congenital lactase deficiency or glucose-galactose malabsorption.
- Malignancies other than NSCLC within 5 years prior to enrollment, except for curatively treated basal cell carcinoma of the skin, early gastrointestinal (GI) cancer by endoscopic resection, in situ carcinoma of the cervix, ductal carcinoma in situ, papillary thyroid cancer, or any cured cancer that is considered to have no impact on disease free survival or overall survival for the current NSCLC
- Any GI disorder that may affect absorption of oral medications, such as malabsorption syndrome or status post-major bowel resection
- Liver disease characterized by aspartate transaminase and alanine transaminase >= 3 × upper limit of normal or impaired excretory function or synthetic function or other conditions of decompensated liver disease such as coagulopathy, hepatic encephalopathy, hypoalbuminemia, ascites, or bleeding from esophageal varices or active viral or active autoimmune, alcoholic, or other types of acute hepatitis
- Japanese patients participating in the serial/intensive PK sample collection only: administration of strong/potent CYP450 3A inhibitors or inducers within 14 days prior to the first dose of study treatment and while on treatment with alectinib up to Week 3
- Any exclusion criteria based on the local labels or guidelines for chemotherapy regimen
- Patients with symptomatic bradycardia
- History of organ transplant
- Known HIV positivity or AIDS-related illness
- Any clinically significant concomitant disease or condition that could interfere with-or for which the treatment might interfere with the conduct of the study or the absorption of oral medications or that would pose an unacceptable risk to the patients in this study, in the opinion of the Principal Investigator
- Any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol requirements and/or follow-up procedures; those conditions should be discussed with the patient before trial entry