ForPatients
by Roche

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

A clinical trial to understand the effect of targeted therapies for patients with non-small cell lung cancer with different mutations (BFAST: Blood First Assay Screening Trial)

A Study to Evaluate the Efficacy and Safety of Multiple Targeted Therapies as Treatments for Participants With Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	27 Countries	NCT03178552 2017-000076-28 BO29554

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/III Multicenter Study Evaluating the Efficacy and Safety of Multiple Targeted Therapies as Treatments for Patients With Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC) Harboring Actionable Somatic Mutations Detected in Blood (B-FAST: Blood-First Assay Screening Trial)

Trial Summary:

This is a phase 2/3, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in combination in participants with unresectable, advanced or metastatic NSCLC determined to harbor oncogenic somatic mutations or positive by tumor mutational burden (TMB) assay as identified by a blood-based next-generation sequencing (NGS) circulating tumor DNA (ctDNA) assay.

Hoffmann-La Roche	Phase 2/Phase 3
Sponsor	Phase

NCT03178552 2017-000076-28 BO29554
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the BFAST clinical trial work? This clinical trial is recruiting people who have a specific type of lung cancer called ‘non--small cell lung cancer’ or NSCLC, which cannot be surgically removed (inoperable).

Changes in genetic material, known as mutations, can cause cancer. There are lots of different types of mutations, and knowing which mutation you have can help your doctor to identify the best treatment for you.

This trial aims to test how well drugs work when they are used to treat lung cancer with different genetic mutations. In order to take part, you must have one of these mutations confirmed by a blood test. **How do I take part in this clinical trial?**
To be able to take part in this clinical trial, you must not have already been given any medicine for your advanced or inoperable cancer.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, they may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

You will have some further blood tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again. If you are not eligible for this clinical trial, the results from your blood tests may be used to see if you are eligible for other clinical trials.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part. While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons. **What treatment will I be given if I join this clinical trial?** Everyone who joins this clinical trial will be split into groups depending on what type of mutation has been found. The treatment you receive will be different based on your mutation:

- *ALK* mutation (known as an anaplastic lymphoma kinase positive, or ALK-positive tumour) will receive a drug called alectinib. This is a tablet that is taken twice a day. *This group is now full. If you are found to have the ALK mutation, you will not be able to take part.*
- *RET* mutation (known as rearranged during transfection positive or RET-positive tumour) will also receive alectinib, but at different doses.

This group is now full. If you are found to have the RET mutation, you will not be able to take part.

- bTMB (known as blood tumour mutational burden) will be split randomly into groups (like flipping a coin) to receive either
    - atezolizumab given once every three weeks as an infusion OR
    - chemotherapy available in a number of different timings depending on which your doctor thinks would be best for you.
      This group is now full. If you are found to have bTMB, you will not be able to take part.
- *ROS1* mutation (also called c-ros oncogene 1) will receive a drug called entrectinib. This is taken by swallowing three capsules together once a day.
  This group is now full. If you are found to have the ROS1 mutation, you will not be able to take part.
- *BRAF* mutation will receive a combination of cobimetinib (three tablets to swallow once a day for three weeks and then no tablets for one week) and vemurafenib (three or four tablets to swallow twice a day). After four weeks of this treatment, you will also receive atezolizumab (infusion once every four weeks).
  This group is now full. If you are found to have the BRAF mutation, you will not be able to take part.
- *EGFR* exon 20 mutation will receive a combination of atezolizumab, bevacizumab, carboplatin, and pemetrexed (all given by infusion once every three weeks). After 4-6 cycles, carboplatin will be stopped and atezolizumab, bevacizumab and pemetrexed treatment will continue indefinitely.
  Screening for this group is currently open.

How often will I be seen in follow-up appointments, and for how long?
You will be given the clinical trial treatment for as long as it can help you. You are free to stop this treatment at any time. After you have completed your treatment, you will still be closely monitored by the clinical trial team, who may follow up with telephone calls, patient medical records, and/or clinic visits approximately every three months. You can choose to withdraw from this follow-up at any time.

What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/show/NCT03178552

Trial-identifier: NCT03178552

Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of unresectable Stage IIIb not amenable to treatment with combined modality chemoradiation (advanced) or Stage IV (metastatic) NSCLC
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- Measurable disease
- Adequate recovery from most recent systemic or local treatment for cancer
- Adequate organ function
- Life expectancy greater than or equal to (>/=) 12 weeks
- For female participants of childbearing potential and male participants, willingness to use acceptable methods of contraception

Exclusion Criteria:

- Inability to swallow oral medication
- Women who are pregnant or lactating
- Symptomatic, untreated CNS metastases
- History of malignancy other than NSCLC within 5 years prior to screening with the exception of malignancies with negligible risk of metastasis or death
- Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction, or cerebrovascular accident within 3 months prior to randomization, unstable arrhythmias, or unstable angina
- Known active or uncontrolled human immunodeficiency virus (HIV) infection
- Either a concurrent condition or history of a prior condition that places the patient at unacceptable risk if he/she were treated with the study drug or confounds the ability to interpret data from the study
- Inability to comply with other requirements of the protocol