NRG Oncology Clinical Trial: NRG-LU003

ALK Inhibitor and/or chemotherapy in Treating Patients With Stage IV ALK Positive Non-Small Cell Lung Cancer based on genetic alterations in their tumor after disease progression (The NCI-NRG Protocol)

About the trial

NRG-LU003 is a clinical trial being led by the National Cancer Institute and NRG Oncology. The goal of the trial is to study the clinical benefit of 2nd or 3rd generation ALK inhibitors in patients whose tumors get worse on a second-generation ALK inhibitor. Treatment will be tailored to genetic changes identified on their tumor biopsy. At this time, it is unknown which targeted therapies or chemotherapy may work better for patients with this type of cancer. NRG-LU003 will be comparing a number of ALK inhibitors including lorlatinib, ceritinib, alectinib, brigatinib, ensartinib, and crizotinib. These targeted therapies may stop the growth of tumor cells by blocking some of the enzymes needed for cancer growth. NRG-LU003 will also be comparing the chemotherapy drugs pemetrexed plus cisplatin, and or carboplatin, to test if chemotherapy may work equal, better or worse in this situation. More specific details about the treatment can be found in the FAQ section below.

About NRG Oncology

As one of the five research groups in the National Cancer Institute’s (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types.

NRG Oncology’s extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI.

To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org.
Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
This study is for people with metastatic lung cancer (specifically a type called non-small cell lung cancer) whose lung cancer also has a change in the gene called “ALK”. Patients in this study must have received treatment with an ALK-targeting drug for their cancer, but the cancer is no longer responding to that treatment.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible study treatments?
There are two parts to this study: screening and treatment. If you decide to take part in this study, your treatment team will perform a fresh biopsy of your tumor and collect a blood sample. If you decide to take part in the treatment part of the study, the treatment you receive will be based on the results of the testing done on the tissue and blood samples collected during the screening part of the study.

How long will I be in this study?
On the study, most treatment cycles repeat every 21 days then, after completion of the study treatment, patients are followed up for 30 days, every 3 months for 2 years, every 6 months for 3 years, and annually thereafter.

Are there side effects?
All biomarker/ALK inhibitors and chemotherapy used in this study may cause side effects. Your doctor will review all of the potential side effects with you before treatment starts. You are encouraged to tell your doctor about any side effects during the study so that they may be treated and so that potential adjustments to the study drugs may be made.

More Information
Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer. You may also call: 1-(800)-4-CANCER (1-800-422-6237)