

ClinicalTrials.gov

IMPORTANT: Listing of a study on this site does not reflect endorsement by the National Institutes of Health. Talk with a trusted healthcare professional before volunteering for a study. [Read more...](#)

Trial record **1 of 1** for: X396-CLI-301

[Previous Study](#) | [Return to List](#) | [Next Study](#)

eXalt3: Study Comparing X-396 (Ensartinib) to Crizotinib in ALK Positive Non-Small Cell Lung Cancer (NSCLC) Patients

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified May 2017 by Xcovery Holding Company, LLC

Sponsor:

Xcovery Holding Company, LLC

Information provided by (Responsible Party):

Xcovery Holding Company, LLC

ClinicalTrials.gov Identifier:

NCT02767804

First received: April 30, 2016

Last updated: May 19, 2017

Last verified: May 2017

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Purpose

The primary purpose of this study is to evaluate the efficacy and safety of X-396 (ensartinib) vs. crizotinib in patients with ALK-positive non-small cell lung cancer that have received up to 1 prior chemotherapy regimen and no prior ALK inhibitor.

Condition	Intervention	Phase
Non-small Cell Lung Cancer	Drug: X-396 (ensartinib) Drug: crizotinib	Phase 3

Study Type: **Interventional**

Study Design: **Allocation: Randomized**

Intervention Model: Parallel Assignment

Masking: No masking

Primary Purpose: Treatment

Official Title: **Phase 3 Randomized Study Comparing X-396 (Ensartinib) to Crizotinib in Anaplastic Lymphoma Kinase (ALK) Positive Non-Small Cell Lung Cancer (NSCLC) Patients**

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [lung cancer](#)

[MedlinePlus](#) related topics: [Lung Cancer](#)

[Drug Information](#) available for: [Crizotinib](#)

[Genetic and Rare Diseases Information Center](#) resources: [Lymphosarcoma](#)

[U.S. FDA Resources](#)

Further study details as provided by Xcovery Holding Company, LLC:

Primary Outcome Measures:

- Progression-free survival (PFS) as assessed by independent radiology review based on RECIST v. 1.1 criteria [Time Frame: 36 months]

Secondary Outcome Measures:

- Overall survival (OS) [Time Frame: 48 months]

- Objective response rate (ORR) based on independent radiology review [Time Frame: 36 months]
- PFS based on investigator assessment [Time Frame: 36 months]
- ORR based on investigator assessment [Time Frame: 36 months]
- Time to response based on independent radiology review [Time Frame: 36 months]
- Time to response based on investigator assessment [Time Frame: 36 months]
- Duration of response based on independent radiology review [Time Frame: 36 months]
- Duration of response based on investigator assessment [Time Frame: 36 months]

Other Outcome Measures:

- CNS response rate based on independent radiology review [Time Frame: 36 months]
- CNS response rate based on investigator assessment [Time Frame: 36 months]
- Time to CNS progression [Time Frame: 36 months]
- Percentage of patients with adverse events [Time Frame: 36 months]
- Patient reported time to deterioration (TTD) as measured by EORTC C30/LC13 QoL questionnaire [Time Frame: 36 months]
- Patient reported TTD as measured by Lung Cancer Symptom Scale (LCSS) [Time Frame: 36 months]
- Patient reported health-related quality of life (HRQoL) as measured by EORTC C30/LC13 QoL questionnaire [Time Frame: 36 months]
- Patient reported HRQoL as measured by LCSS [Time Frame: 36 months]
- Plasma concentrations (Cmax) at participating sites [Time Frame: 36 months]
- Plasma concentrations (Cmin) at participating sites [Time Frame: 36 months]

Estimated Enrollment: 402
 Study Start Date: June 2016
 Estimated Study Completion Date: April 2020
 Estimated Primary Completion Date: April 2020 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Experimental: X-396 (ensartinib) Eligible patients with ALK+ NSCLC will receive oral X-396 (ensartinib) at 225mg QD with or without food until progression or unacceptable toxicity develops	Drug: X-396 (ensartinib) oral ALK inhibitor
Active Comparator: crizotinib Eligible patients with ALK+ NSCLC will receive oral crizotinib at 250mg BID with or without food until progression or unacceptable toxicity develops	Drug: crizotinib oral ALK inhibitor Other Name: Xalkori

Detailed Description:

To evaluate the efficacy and safety of X-396 (ensartinib) vs. crizotinib in patients with ALK-positive NSCLC that have received up to 1 prior chemotherapy regimen and no prior ALK tyrosine kinase inhibitor (TKI), to obtain additional pharmacokinetic (PK) data from sparse PK sampling, to compare the quality of life (QoL) in patients receiving X-396 vs. crizotinib, to evaluate the status of exploratory biomarkers and correlate with clinical outcome, and to obtain germline DNA samples for possible pharmacogenetic analysis in the event that outliers with respect to efficacy, tolerability/safety, or exposure are identified.

▶ Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
 Sexes Eligible for Study: All
 Accepts Healthy Volunteers: No

Criteria

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. Patients may have received up to 1 prior chemotherapy regimen, which may also include maintenance therapy.
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) score of 0 to 2.
- Life expectancy of at least 12 weeks.
- Ability to swallow and retain oral medication.
- Adequate organ system function.
- Brain metastases allowed if asymptomatic at study baseline.
- Men willing to use adequate contraceptive measures.
- Women who are not of child-bearing potential, and women of child-bearing potential who agree to use adequate contraceptive measures and who have a negative serum or urine pregnancy test.
- Patients must be at least 18 years of age.

- Patients must have measurable disease per RECIST v. 1.1.
- Patients must be ALK-positive by IHC.
- Willingness and ability to comply with the trial and follow-up procedures.
- Ability to understand the nature of this trial and give written informed consent.

Exclusion Criteria:

- Patients that have previously received an ALK TKI, and patients currently receiving cancer therapy.
- Use of an investigational drug within 21 days prior to the first dose of study drug.
- Any chemotherapy within 4 weeks, or major surgery or radiotherapy within the last 14 days.
- Patients with primary CNS tumors and leptomeningeal disease are ineligible.
- Patients with a previous malignancy within the past 3 years.
- Concomitant use of drugs with a risk of causing Torsades de Pointes. -Concomitant use of herbal medications.
- Patients receiving strong CYP3A inhibitors or inducers.
- Women who are pregnant or breastfeeding.
- Presence of active gastrointestinal (GI) disease or other condition that will interfere significantly with the absorption, distribution, metabolism, or excretion of study medications.
- Clinically significant cardiovascular disease.
- Patients who are immunosuppressed (including known HIV infection), have a serious active infection at the time of treatment, have interstitial lung disease/pneumonitis, or have any serious underlying medical condition that would impair the ability of the patient to receive protocol treatment.
- Psychological, familial, sociological, or geographical conditions that do not permit compliance with the protocol.
- Concurrent condition that in the investigator's opinion would jeopardize compliance with the protocol or would impart excessive risk associated with study participation that would make it inappropriate for the patient to be enrolled.
- Inability or unwillingness to comply with study and/or follow-up procedures outlined in the protocol.

▶ Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02767804

Contacts

Contact: Jolee D. Holt, RN 918-899-1012 jholt@optimalsites.net
 Contact: Holly Hoefler, MSHC 918-899-1012 optimalcommunity@optimalsites.net

+ Show 69 Study Locations

Sponsors and Collaborators

Xcovery Holding Company, LLC

▶ More Information

Responsible Party: Xcovery Holding Company, LLC
 ClinicalTrials.gov Identifier: [NCT02767804](#) [History of Changes](#)
 Other Study ID Numbers: **X396-CLI-301**
 Study First Received: April 30, 2016
 Last Updated: May 19, 2017

Keywords provided by Xcovery Holding Company, LLC:
 ALK-positive NSCLC

Additional relevant MeSH terms:

Lung Neoplasms	Respiratory Tract Diseases
Carcinoma, Non-Small-Cell Lung	Carcinoma, Bronchogenic
Respiratory Tract Neoplasms	Bronchial Neoplasms
Thoracic Neoplasms	Crizotinib
Neoplasms by Site	Protein Kinase Inhibitors
Neoplasms	Enzyme Inhibitors
Lung Diseases	Molecular Mechanisms of Pharmacological Action

ClinicalTrials.gov processed this record on June 12, 2017

