Protocol Title: Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein

Target Population: Stage IB-IIIA Non-Small Cell Lung Cancer that has been removed by surgery and has a mutation in Anaplastic Lymphoma Kinase (ALK) Protein.

Summary: To evaluate whether adjuvant therapy with Crizotinib will result in improved Overall Survival (OS) over placebo for patients with Stage IB ≥ 4 cm, II, and IIIA, ALK-Positive Non-Small Cell Lung Cancer (NSCLC) following surgical resection.

Key Inclusion Criteria:
- Patients must have undergone complete surgical resection of their Stage IB (≥ 4 cm), II, or Non-Squamous IIIA NSCLC per AJCC 7th edition and have had Negative Margins.
  - N3 Disease is NOT allowed.
- Patients must be registered to the ALCHEMIST-SCREEN (ALLIANCE A151216) Trial prior to randomization.
- Positive for translocation or inversion events involving the ALK Gene Locus (e.g. resulting in echinoderm microtubule associated protein like 4 [EML4]-ALK Fusion) as determined by the Vysis Break Point FISH Assay and defined by an increase in the distance between 5’ and 3’ ALK probes or the loss of the 5’ probe.
  - This must have been performed:
    - By a local Clinical Laboratory Improvement Amendments (CLIA) certified laboratory.
    - Patient registered to and the ALK Fusion status performed centrally on the ALCHEMIST-SCREEN (ALLIANCE A151216).
- No known Interstitial Fibrosis or Interstitial Lung Disease.
- No prior treatment with Crizotinib or another ALK Inhibitor.
- No ongoing Cardiac Dysrhythmias of Grade ≥ 2.
- No use of medications, herbs, or foods that are known potent Cytochrome P450, subfamily 3A, polypeptide 4 (CYP3A4) Inhibitors or Inducers.
- Minimum time requirement between date of surgery and randomization must be at least 4 Weeks (28 Days).
- Maximum time requirement between surgery and randomization must be:
  - 3 Months (90 Days) if no adjuvant chemotherapy was administered.
  - 8 Months (240 Days) if adjuvant chemotherapy was administered.
  - 10 Months (300 Days) if adjuvant chemotherapy and radiation therapy were administered.
- Patients must have completed any prior adjuvant chemotherapy or radiation therapy 2 or more Weeks (6 or more Weeks for Mitomycin and Nitrosoureas) prior to randomization and be adequately recovered at the time of randomization.
- NOTE: Patients taking low dose Methotrexate for non-malignant conditions and other cytotoxic agents for non-malignant conditions are allowed to continue treatment while on study.
- NOTE: Neo-adjuvant chemotherapy or radiation therapy for the resected lung cancer is NOT permitted.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02201992