Crizotinib in Treating Patients With Stage IB-IIIA Non-small Cell Lung Cancer That Has Been Removed by Surgery and ALK Fusion Mutations (An ALCHEMIST Treatment Trial)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have undergone complete surgical resection of their stage IB (\>= 4 cm), II, or non-squamous IIIA NSCLC per American Joint Committee on Cancer (AJCC) 7th edition and have had negative margins; N3 disease is not allowed * Baseline chest computed tomography (CT) with or without contrast must be performed within 6 months (180 days) prior to randomization to ensure no evidence of disease; if clinically indicated additional imaging studies must be performed to rule out metastatic disease * Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 * 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 fluorescence in situ hybridization (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: report must indicate the results as well as the CLIA number of the laboratory which performed the assay; tissue must be available for submission for central, retrospective confirmation of the ALK fusion status via ALCHEMIST-SCREEN (ALLIANCE A151216) OR * Patient registered to and the ALK fusion status performed centrally on the ALCHEMIST-SCREEN (ALLIANCE A151216) * Women must not be pregnant or breast-feeding * All females of childbearing potential must have a blood or urine pregnancy test within 72 hours prior to randomization to rule out pregnancy; a female of childbearing potential is any woman, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Women of childbearing potential and sexually active males must be strongly advised to practice abstinence or use an accepted and effective method of contraception * Patients must NOT have uncontrolled intercurrent illness including, but not limited to, serious ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, uncontrolled cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements * No known interstitial fibrosis or interstitial lung disease * No prior treatment with crizotinib or another ALK inhibitor * No ongoing cardiac dysrhythmias of grade \>= 2 National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.0, uncontrolled atrial fibrillation (any grade), or corrected QT (QTc) interval \> 470 msec * No use of medications, herbals, or foods that are known potent cytochrome P450, subfamily 3A, polypeptide 4 (CYP3A4) inhibitors or inducers, included but not limited to those outlined * Patients must be adequately recovered from surgery at the time of randomization * The minimum time requirement between date of surgery and randomization must be at least 4 weeks (28 days) * The 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 * Serum aspartate aminotransferase (AST) and serum alanine aminotransferase (ALT) =\< 2.5 x upper limit of normal (ULN) * Total serum bilirubin =\< 1.5 x ULN * Absolute neutrophil count (ANC) \>= 1500/mm\^3 * Platelets \>= 30,000/mm\^3 * Hemoglobin \>= 8.0 g/dL * Serum creatinine =\< 2 x ULN * Prior to randomization patients with any non-hematologic toxicity from surgery, chemotherapy, or radiation must have recovered to grade =\< 1 with the exception of alopecia and the criteria outlined * Patients must not have any history of locally advanced or metastatic cancer requiring systemic therapy within 5 years from randomization, with the exception of in-situ carcinomas and non-melanoma skin cancer; patients must have no previous primary lung cancer diagnosed concurrently or within the past 2 years * Patients may not be receiving any other investigational agents while on study

Conditions & Interventions

Interventions:

OTHER: Clinical Observation, DRUG: Crizotinib, OTHER: Laboratory Biomarker Analysis

Conditions:

ALK Gene Rearrangement, ALK Gene Translocation, ALK Positive, Stage IB Non-Small Cell Lung Carcinoma AJCC v7, Stage II Non-Small Cell Lung Cancer AJCC v7, Stage IIA Non-Small Cell Lung Carcinoma AJCC v7, Stage IIB Non-Small Cell Lung Carcinoma AJCC v7, Stage IIIA Non-Small Cell Lung Cancer AJCC v7

More Information

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