# Clinical Trials Data ALK - Document 16

# Combination Checkpoint Inhibitor Plus Erlotinib or Crizotinib for EGFR or ALK Mutated Stage IV Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01998126

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosis of Stage IV Non-Small Cell Lung Cancer (NSCLC), or Stages II - III NSCLC that cannot be treated curatively with standard techniques.\n\* Non-Small Cell Lung Cancer (NSCLC) that is either EGFR or ALK mutated.\n\* Untreated with/or actively treated with specific inhibitor for less than 6 months if not progressing on active therapy.\n\* Age \\> 18.\n\* ECOG performance status 0, 1 or 2.\n\* Prior chemotherapy is allowed if \\> one month from the end of treatment. Patients must not have received chemotherapy within 4 weeks of the start of study drug.\n\* Brain metastases are allowed if the patient is asymptomatic or previous steroid treatment was discontinued \\> 6 weeks.\n\* Adequate bone marrow function as defined in the protocol\n\* Serum bilirubin levels \\< 1.5 mg/dL except for patients with Gilbert's syndrome.\n\* Adequate organ function as defined in the protocol\n\* If female and of childbearing potential, documentation of negative pregnancy test (serum or urine) within 7 days prior to first dose.\n\* Able to provide informed consent and have signed an approved consent form that conforms to federal and institutional guidelines.\n\nExclusion Criteria:\n\n\* Concurrent therapy with any other non-protocol anti-cancer therapy.\n\* History of any other malignancy requiring active treatment.\n\* Patients who have had a history of acute diverticulitis, intra-abdominal abscess, Gastrointestical obstruction and abdominal carcinomatosis which are known risk factors for bowel perforation.\n\* History of symptomatic autoimmune disease (e.g., rheumatoid arthritis, systemic progressive sclerosis \\[scleroderma\\], systemic lupus erythematosus, autoimmune vasculitis \\[e.g., Wegener's Granulomatosis\\]); motor neuropathy considered of autoimmune origin (e.g., Guillain-Barre Syndrome). History of vitiligo and adequately controlled endocrine deficiencies such as hypothyroidism are allowed.\n\* Significant cardiovascular disease including:\n\* Active, clinically symptomatic left ventricular failure.\n\* Uncontrolled symptomatic hypertension that cannot be controlled with anti-hypertensive agents.\n\* Myocardial infarction, severe angina, or unstable angina within 6 months prior to administration of first dose of study drug.\n\* History of serious ventricular arrhythmia (i.e., ventricular tachycardia or ventricular fibrillation)\n\* Cardiac arrhythmias requiring anti-arrhythmic medications (except for atrial fibrillation that is well controlled with anti-arrhythmic medication)\n\* Coronary or peripheral artery bypass graft within 6 months of screening.\n\* Uncontrolled CNS metastases are not allowed; subjects with previously treated brain metastases will be allowed if the brain metastases have been treated, toxicities have resolved to grade 1 or baseline and steroids are no longer required. Leptomeningeal metastases are not allowed.\n\* Serious/active infection or infection requiring parenteral antibiotics.\n\* Pregnant or lactating females.\n\* HIV infection or chronic hepatitis B or C. Negative Screening tests for HIV, Hepatitis B, and Hepatitis C are required.\n\* The presence of any other medical or psychiatric disorder that, in the opinion of the treating physician, would contraindicate the use of the drugs in this protocol or place the subject at undue risk for treatment complications.",  
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"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
Yes, a patient with an ALK gene mutation would be eligible for the clinical trial described. The inclusion criteria specifically state that patients with Non-Small Cell Lung Cancer (NSCLC) that is either EGFR or ALK mutated are eligible for the trial. Assuming the patient meets all other inclusion and exclusion criteria, they would be able to participate.