# Clinical Trials Data ALK - Document 6

# Crizotinib and Ganetespib (STA-9090) in ALK Positive Lung Cancers

## Clinical Trial: https://clinicaltrials.gov/study/NCT01579994

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically proven diagnosis confirmed at MSKCC of advanced lung adenocarcinoma that is locally advanced or metastatic (stage III/IV).\n\* Positive for translocation or inversion events involving the ALK gene locus as determined standard methods (including but not limited to by FISH and IHC testing).\n\* No prior treatment with crizotinib, but they may have received prior cytotoxic chemotherapy.\n\* Age \u2265 18 years.\n\* Measurable (RECIST 1.1) indicator lesion not previously irradiated.\n\* Karnofsky Performance Status \u2265 70%\n\* Able to take oral medications\n\* A negative serum pregnancy test obtained within two weeks prior to administration of the experimental agents in all pre-menopausal women (last menstrual period \u2264 24 months ago).\n\* All women of child bearing potential (WOCBP) and sexually active men must agree to use adequate methods of birth control throughout the study which include use of oral contraceptives with an additional barrier method, double barrier methods (diaphragm with spermicidal gel or condoms with contraceptive foam), Depo-Provera, partner vasectomy and/or tubal libation and total abstinence.\n\nExclusion Criteria:\n\n\* Prior crizotinib therapy\n\* Inadequate recovery from any toxicity related to prior treatment (to Grade 1 or baseline).\n\* Inadequate hematologic function defined as:\n\n \* Absolute neutrophil count (ANC) \\< 1,000 cells/mm\u00b3.\n \* Platelet count \\< 75,000/mm\u00b3\n \* Hemoglobin \\< 9.0g/dL.\n\nInadequate hepatic function defined by:\n\n\* AST and/or ALT \\> 3x upper limited of normal (ULN).\n\* Total bilirubin \\> 2x ULN.\n\* Alkaline phosphatase \\> 3x ULN.\n\* Patients with hepatic metastases may have ALT/AST \u2264 5x ULN.\n\* Patients with hepatic and/or bone metastases may have an AP \u2264 5x ULN.\n\* Inadequate renal function defined by serum creatinine \\> 2x ULN Uncontrolled systemic fungal, bacterial, viral or other infection (defined as exhibiting ongoing signs/symptoms related to infection without improvement, despite appropriate anti-infective medications or other treatment).\n\* Patients with clinically active brain metastasis (requiring therapy with steroids or radiation therapy). Patients with clinically stable brain metastases (previously treated or untreated) for two weeks are eligible.\n\* Significant cardiac disease (e.g. New York Heart Association (NYHA) Class 3 or 4; myocardial infarction within the past 6 months; unstable angina; coronary angioplasty or coronary artery bypass graft (CABG) within the past 6 months; or uncontrolled atrial or ventricular cardiac arrhythmias).\n\* Previously or current malignancies at other sites within the last 2 years, with the exception of adequately treated in situ carcinoma of the cervix, basal or squamous cell carcinoma of the skin, or prostate cancer that does not require active treatment per National Comprehensive Cancer Network (NCCN) guidelines.\n\* Women who are pregnant or lactating\n\* Use of drugs or food that are known potent CYP3A4 inhibitors (see Appendix C)\n\* Use of drugs that are known potent CYP3A4 inducers (see Appendix D)\n\* Any other condition that, in the opinion of the Investigator, may compromise the safety, compliance of the patient, or would preclude the patient from successful completion of the study.",  
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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:  
A patient with an ALK gene mutation \*could\* be eligible for this trial, but it depends on several other factors. The trial explicitly requires a positive ALK translocation or inversion, which is a specific type of ALK gene alteration. Simply having \*any\* ALK mutation isn't enough.  
  
Here's a breakdown:  
  
\*\*Factors that make the patient potentially eligible:\*\*  
  
\* \*\*ALK gene translocation/inversion:\*\* The patient's ALK alteration must specifically be a translocation or inversion involving the ALK gene locus.  
  
\*\*Factors that could make the patient ineligible:\*\*  
  
\* \*\*Prior crizotinib therapy:\*\* The patient cannot have received crizotinib before.  
\* \*\*Other health conditions:\*\* The patient must meet specific requirements regarding blood counts, liver and kidney function, prior treatments, and other medical conditions (e.g., no active brain metastasis requiring treatment, no significant cardiac disease).  
\* \*\*Current medications:\*\* The patient cannot be taking certain medications that interact with CYP3A4.  
\* \*\*Pregnancy/Lactation:\*\* Pregnant or lactating women are excluded.  
\* \*\*Other cancers:\*\* History of other malignancies within the last 2 years (with some exceptions).  
  
  
In short, the ALK translocation/inversion is a necessary but not sufficient condition for eligibility. A full evaluation based on all inclusion and exclusion criteria is required to determine if the patient qualifies.