# Clinical Trials Data ALK - Document 25

# Phase 1/2 Study of X-396, an Oral ALK Inhibitor, in Patients With ALK-positive Non-Small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01625234

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Histologically or cytologically confirmed diagnosis of advanced solid tumor malignancy. Patients may be ALK TKI-naive or may have received prior crizotinib and/or second generation ALK TKIs. In addition, patients with a known ALK 1198 mutation will be allowed.\n\n -For the expanded cohort portion of the study, patients must have NSCLC with ALK genomic alterations; however, patients will be allowed to enroll based on local FDA-approved ALK results.\n2. Eastern Cooperative Group ECOG) Performance Status score of 0 or 1.\n3. Ability to swallow and retain oral medication.\n4. Adequate organ system function.\n5. Patients with treated or untreated asymptomatic CNS metastases may be allowed to enroll.\n6. Male patients willing to use adequate contraceptive measures.\n7. Female patients who are not of child-bearing potential, and female patients of child-bearing potential who agree to use adequate contraceptive measures.\n8. Patients must be \u2265 18 years of age.\n9. Patients must have measurable or evaluable disease for the dose escalation portion of the study and measurable disease for the expanded cohort portion of the study (except for patients in the CNS metastases and leptomeningeal cohorts).\n10. Willingness and ability to comply with the trial and follow-up procedures.\n11. Ability to understand the nature of this trial and give written informed consent.\n\nExclusion Criteria:\n\n1. Patients currently receiving cancer therapy.\n2. Use of an investigational drug within 21 days or 5 half-lives (whichever is shorter) prior to the first dose of X-396. A minimum of 10 days between treatment and X-396 and 2 days between ALK TKI and X-396.\n3. Any major surgery, radiotherapy, or immunotherapy within the last 21 days (focal radiation does not require a washout period; \u22654 weeks for WBRT). Chemotherapy regimens with delayed toxicity within the last 4 weeks. Chemotherapy regimens given continuously or on a weekly basis with limited potential for delayed toxicity within the last 2 weeks.\n4. Prior stem cell transplant.\n5. Patients with a known allergy or delayed hypersensitivity reaction to drugs chemically related to X-396 (e.g., crizotinib) or to the active ingredient of X-396.\n6. Patients with primary CNS tumors are ineligible.\n7. Patients receiving CYP3A substrates with narrow therapeutic indices, strong CYP3A inhibitors, and strong CYP3A inducers.\n8. Concomitant use of herbal medications at least 7 days prior to the first dose of study drug and throughout participation in the trial.\n9. Females who are pregnant or breastfeeding.\n10. Presence of active gastrointestinal (GI) disease or other condition that will interfere significantly with the absorption, distribution, metabolism, or excretion of X-396.\n11. Clinically significant cardiovascular disease.\n12. Patients who are immunosuppressed (including known HIV infection), have a serious active infection at the time of treatment, have known hepatitis C, or have any serious underlying medical condition that would impair the ability of the patient to receive protocol treatment.\n13. Psychological, familial, sociological, or geographical conditions that do not permit compliance with the protocol.\n14. 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.\n15. Inability or unwillingness to comply with study and/or follow-up procedures outlined in the protocol.",  
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"ADULT",  
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]

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 \*only\* an ALK gene mutation might be eligible, but it's not guaranteed based on this text. Here's why:  
  
\* \*\*Inclusion Criteria 1 is complex:\*\* It states that patients with advanced solid tumor malignancies are eligible, and can be ALK TKI-naive \*or\* have received prior ALK TKIs. The inclusion of patients with a known ALK 1198 mutation suggests ALK mutations are of interest. \*However\*, the expanded cohort specifically requires NSCLC (Non-Small Cell Lung Cancer) with ALK genomic alterations.  
  
\* \*\*The ambiguity:\*\* Having an ALK mutation doesn't automatically qualify someone if their cancer isn't NSCLC. They might be eligible for the initial part of the study if they have another type of advanced solid tumor malignancy with an ALK mutation, but they would be excluded from the expanded cohort.  
  
Therefore, a patient with an ALK mutation needs to have an advanced solid tumor malignancy to be considered. If that malignancy is NSCLC, then they are likely eligible. If it's a different type of cancer, they \*might\* be eligible for the initial phase but not the expanded cohort. Confirmation with the trial investigators is essential for accurate determination of eligibility.