# Clinical Trials Data ALK - Document 13

# LDK378 in Adult Chinese Patients With ALK-rearranged (ALK-positive) Advanced Non-small Cell Lung Cancer (NSCLC) Previously Treated With Crizotinib

## Clinical Trial: https://clinicaltrials.gov/study/NCT02040870

"eligibilityCriteria": "Inclusion criteria:\n\n\* Histologically or cytologically confirmed diagnosis of NSCLC that carries an ALK rearrangement defined as positive using the FDA approved Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.) test and scoring algorithm (including positivity criteria) or positive as assessed by the CFDA approved immunohistochemistry (IHC) test (Ventana Medical Systems, Inc)\n\* Age 18 years or older at the time of informed consent.\n\* Patients must have stage IIIB or IV NSCLC at the time of study entry and have had progressive disease during or after crizotinib treatment whether or not previously treated with cytotoxic chemotherapy. If treated with chemotherapy, maximum 2 lines are allowed.\n\nExclusion Criteria:\n\n\* Patients with known hypersensitivity to any of the excipients of LDK378\n\* Patients with symptomatic central nervous system (CNS) metastases who are neurologically unstable or have required increasing doses of steroids within the 2 weeks prior to study entry to manage CNS symptoms\n\* History of carcinomatous meningitis\n\* Presence or history of a malignant disease other than NSCLC that has been diagnosed and/or required therapy within the past 3 years.\n\* clinically significant, uncontrolled heart disease.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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 \*might\* be eligible. Here's why it's not a definite yes:  
  
\* \*\*ALK rearrangement vs. ALK mutation:\*\* The trial specifies "ALK rearrangement" confirmed by specific tests. While an ALK mutation often leads to rearrangement, they aren't perfectly synonymous. The trial requires the specific rearrangement detectable by the mentioned tests. A patient could have an ALK mutation that doesn't result in a rearrangement detectable by these tests, making them ineligible.  
\* \*\*Progression after crizotinib:\*\* The trial is specifically for patients who have progressed \*during or after\* crizotinib treatment. Simply having the ALK rearrangement is not enough. They must have received this specific prior therapy.  
\* \*\*Other criteria:\*\* The patient must also meet all other inclusion criteria (age, NSCLC stage, etc.) and \*not\* meet any exclusion criteria.  
  
Therefore, having an ALK mutation is a necessary but \*insufficient\* condition for eligibility. Confirmation of the specific ALK rearrangement by the required tests and progression on crizotinib treatment are crucial.