# 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:  
Based on the provided eligibility criteria, a patient with an ALK (anaplastic lymphoma kinase) gene mutation would be eligible for this clinical trial, provided they meet all of the inclusion criteria and none of the exclusion criteria. The key inclusion criterion specifies that the non-small cell lung cancer (NSCLC) must carry an ALK rearrangement, as confirmed by an FDA-approved or CFDA-approved test. Other requirements include being 18 years or older, having stage IIIB or IV NSCLC with progressive disease after crizotinib treatment, and having had no more than two lines of cytotoxic chemotherapy.  
  
If the patient meets all these inclusion criteria and does not fall into any of the exclusion categories, such as having a hypersensitivity to excipients of LDK378, uncontrolled CNS metastases, carcinomatous meningitis, another recent malignancy, or significant uncontrolled heart disease, then they would be eligible for the trial.