# Clinical Trials Data ALK - Document 7

# Phase I Study of LDK378 in Pediatric, Malignancies With a Genetic Alteration in Anaplastic Lymphoma Kinase (ALK)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01742286

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosed with a locally advanced or metastatic malignancy that has progressed despite standard therapy, or for which no effective standard therapy exists\n\* Age \u2265 12 months and \\< 18 years\n\* The tumor must carry a genetic alteration of ALK\n\* Patients must have evaluable or measurable disease.\n\* Karnofsky performance status score \u2265 60% for patients \\> 12 years of age; Lansky score \u2265 50% for patients \u2264 12 years of age.\n\nExclusion criteria:\n\n\* Symptomatic central nervous system (CNS) metastases who are neurologically unstable or require increasing doses of steroids or local CNS-directed therapy (such as radiotherapy, surgery or intrathecal chemotherapy) to control their CNS disease\n\* Inadequate end organ function as defined by specified laboratory values\n\* Body surface area (BSA) \\< 0.35 m2\n\* Impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of LDK378 (e.g., ulcerative diseases, uncontrolled nausea, vomiting, diarrhea, or malabsorption syndrome)\n\* Use of medications that are known to be strong inhibitors or inducers of CYP3A4/5 that cannot be discontinued at least 1 week prior to start of treatment with LDK378 and for the duration of the study\n\* Use of medications that are mainly metabolized by CYP3A4/5 or CYP2C9 that cannot be discontinued at least 1 week prior to start of treatment with LDK378 and for the duration of the study\n\* History of interstitial lung disease or interstitial pneumonitis, including clinically significant radiation pneumonitis\n\* History of pancreatitis or history of increased amylase or lipase that was due to pancreatic disease.\n\* Medications with a known risk of prolongation of QT interval",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "12 Months",  
"stdAges": [  
"CHILD"  
]

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 inclusion criteria provided, a patient with an ALK gene mutation would be eligible for the clinical trial, provided they meet all other inclusion and exclusion criteria. Here is a summary that supports this conclusion:  
  
1. \*\*Inclusion Criteria Related to ALK Mutation:\*\*  
 - The trial specifically requires that "The tumor must carry a genetic alteration of ALK." Therefore, having an ALK gene mutation is a key eligibility requirement.  
   
2. \*\*Other Inclusion Criteria:\*\*  
 - The patient must have a locally advanced or metastatic malignancy that has progressed, or for which no effective standard therapy exists.  
 - The patient must be between 12 months and less than 18 years of age.  
 - The patient must have evaluable or measurable disease.  
 - The patient's performance status must meet specific requirements (Karnofsky score or Lansky score).  
  
3. \*\*Exclusion Criteria:\*\*  
 - Ensure the patient does not have symptomatic CNS metastases, inadequate end organ function, a body surface area below 0.35 m², gastrointestinal impairments that affect absorption, or other listed medical conditions and medication conflicts.  
  
As long as the patient meets all the inclusion criteria and none of the exclusion criteria apply, they would be eligible for the trial.