# Clinical Trials Data ALK - Document 2

# AUY922 for Advanced ALK-positive NSCLC

## Clinical Trial: https://clinicaltrials.gov/study/NCT01752400

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed advanced NSCLC\n\* Tumor characterized by abnormalities in ALK\n\* Required to provide archival tissue in the form of 5 formalin fixed paraffin embedded sections\n\* Have acquired resistance to treatment with an ALK-TKI\n\* At least one measurable lesion as defined by RECIST criteria\n\* Life expectancy of at least 12 weeks\n\nExclusion Criteria:\n\n\* Pregnant or breastfeeding\n\* Discontinued ALK TKI more than four weeks prior to enrollment\n\* Unresolved diarrhea greater than or equal to CTCAE grade 1\n\* Not willing to use double barrier methods of contraception\n\* Prior anti-neoplastic treatment with any HSP90 or HDAC inhibitor compound\n\* Have received cytoxic chemotherapy in the intervening period since discontinuation of an ALK-TKI\n\* Have undergone major surgery within 2 weeks prior to starting study drug\n\* Any concurrent or uncontrolled illness\n\* Any known disorders due to a deficiency in bilirubin glucuronidation\n\* Taking therapeutic doses of warfarin\n\* Any serious cardiac disorders or abnormalities\n\* Concurrent malignancies or invasive cancers diagnosed within the past 2 years except for adequately treated basal cell cancer of the skin or in situ cancers\n\* Known to be HIV positive\n\* Known hypersensitivity to any of the study drugs or their excipients\n\* Participation in another clinical study within 30 days before the first study treatment",  
 "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 for the clinical trial, a patient with an ALK gene mutation would indeed be eligible for the trial, provided they meet all the inclusion criteria and none of the exclusion criteria.  
  
### Eligibility Points:  
  
- \*\*Inclusion Criteria\*\*:  
 - The patient must have advanced non-small cell lung cancer (NSCLC) with abnormalities in the ALK gene, which applies to this patient since they have an ALK gene mutation.  
 - The patient is required to have acquired resistance to treatment with an ALK-TKI.  
 - They must have at least one measurable lesion as defined by RECIST criteria.  
 - They need a life expectancy of at least 12 weeks.  
 - They must provide archival tissue as specified.  
  
- \*\*Exclusion Criteria\*\*:  
 - The patient should not be pregnant or breastfeeding.  
 - They must not have discontinued ALK TKI more than four weeks before enrollment.  
 - The patient should not have unresolved diarrhea greater than or equal to CTCAE grade 1.  
 - They must be willing to use double barrier methods of contraception if applicable.  
 - They should not have had prior anti-neoplastic treatment with any HSP90 or HDAC inhibitor compound.  
 - The patient must not have received cytotoxic chemotherapy after discontinuing the ALK-TKI.  
 - No major surgery should have occurred within 2 weeks prior to starting the trial drug.  
 - The patient should not have any concurrent or uncontrolled illness, serious cardiac disorders, or known disorders related to bilirubin glucuronidation.  
 - They should not be taking therapeutic doses of warfarin.  
 - They should not have concurrent malignancies or invasive cancers diagnosed within the last 2 years, barring specific exceptions such as treated basal cell skin cancer or in situ cancers.  
 - The patient cannot be known to be HIV positive, have a known hypersensitivity to study drugs, or have participated in another study within 30 days before the first treatment.  
  
If the patient with an ALK gene mutation meets all the required inclusion criteria and does not meet any of the exclusion criteria, they would be eligible for the trial.