# Clinical Trials Data EGFR - Document 96

# Phase 2 Study of AUY922 in NSCLC Patients With Exon 20 Insertion Mutations in EGFR

## Clinical Trial: https://clinicaltrials.gov/study/NCT01854034

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologically or cytologically confirmed stage IV or recurrent NSCLC\n\* Measurable disease by RECIST 1.0\n\* Must have received at least one prior line of therapy for advanced lung cancer (no maximum number)\n\* Life expectancy of at least 12 weeks\n\nExclusion Criteria:\n\n\* Pregnant or breastfeeding\n\* Radiation within 2 weeks\n\* Cytotoxic chemotherapy or monoclonal antibodies within 4 weeks\n\* EGFR tyrosine kinase inhibitor within 2 weeks\n\* Other small molecule inhibitor within 2 weeks\n\* Experimental treatment within 30 days\n\* Prior treatment with any HSP90 or HDAC inhibitor compound\n\* Known and untreated brain metastases\n\* History of allergic reactions attributed to compounds of similar chemical or biologic composition to AUY922\n\* Unresolved diarrhea greater than or equal to CTCAE version 4, grade 1\n\* Major surgery within 2 weeks of starting study drug or have not recovered from side effects of surgery\n\* Known disorders due to a deficiency in bilirubin glucuronidation\n\* Requiring use of therapeutic doses of warfarin (Coumadin)\n\* History of long QT syndrome\n\* History of clinically manifest ischemic heart disease, heart failure or left ventricular dysfunction\n\* Clinically significant ECG abnormalities\n\* Other clinically significant heart disease\n\* Currently receiving treatment with any medication which has a relative risk of prolonging the QTc interval or inducing Torsades de Pointes\n\* On a cardiac pacemaker\n\* Concurrent malignancies or invasive cancers diagnosed within 3 years except for adequately treated basal cell cancer of the skin or in situ cancer of the cervix\n\* Known to be HIV positive",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
The provided criteria \*\*do not exclude\*\* patients with EGFR mutations. While the exclusion criteria list several timeframes related to prior targeted therapies (including EGFR TKIs), having the mutation itself is not a barrier to entry. In fact, some trials specifically target patients \*with\* EGFR mutations. This trial allows patients who have had prior EGFR TKI treatment as long as it was stopped at least 2 weeks prior to enrollment.