# Clinical Trials Data EGFR - Document 36

# Multicenter Study of Rociletinib Administered to Patients With Previously Treated Mutant EGFR Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02147990

"eligibilityCriteria": "Inclusion Criteria\n\n\* Histologically or cytologically confirmed metastatic or unresectable locally advanced NSCLC\n\* Documented evidence of a tumor with 1 or more EGFR mutations excluding exon 20 insertion\n\* Disease progression confirmed by radiologic assessment while receiving treatment with the first single agent EGFR-TKI\n\* EGFR TKI treatment discontinued less than or equal to 30 days prior to planned initiation of rociletinib\n\* The washout period for an EGFR inhibitor is a minimum of 3 days\n\* No intervening treatment between cessation of single agent EGFR TKI and planned initiation of rociletinib\n\* Previous treatment with less than or equal to 1 prior chemotherapy (excluding prior neo-adjuvant or adjuvant chemotherapy or chemoradiotherapy with curative intent)\n\* Any toxicity related to prior EGFR inhibitor treatment must have resolved to Grade 1 or less\n\* Central laboratory confirmation of the presence of the T790M mutation in tumor tissue in Cohort A and the presence or absence of the T790M mutation in tumor tissue in Cohort B. Centrally indeterminate, unknown or invalid specimens are not acceptable. Biopsy material obtained from either primary or metastatic tumor tissue and sent to the central laboratory must be within 60 prior to dosing study drug but following disease progression on the first EGFR TKI\n\* Measurable disease according to RECIST Version 1.1\n\* Life expectancy of at least 3 months\n\* ECOG performance status of 0 to 1\n\* Minimum Age 18 years (in certain territories, the minimum age requirement may be higher eg age 20 years in Japan and Taiwan)\n\* Adequate hematological and biological function, confirmed by defined laboratory values\n\* Written consent on an IRB/IEC-approved Informed Consent Form (ICF) prior to any study specific evaluation\n\nExclusion Criteria\n\n\* Documented evidence of an exon 20 insertion activating mutation in the EGFR gene\n\* Active second malignancy i.e. patient known to have potentially fatal cancer present for which he/she may be (but not necessarily) currently receiving treatment\n\* Patients with a history of malignancy that has been completely treated, with no evidence of that cancer currently, are permitted to enrol in the trial provided all chemotherapy was completed greater than 6 months prior and/or bone marrow transplant greater than 2 years prior\n\* Known pre-existing interstitial lung disease\n\* Cohort A only: Patients with leptomeningeal carcinomatosis are excluded. Other central nervous system (CNS) metastases are only permitted if treated, asymptomatic, and stable (not requiring steroid for at least 4 weeks prior to the start of study treatment). Cohort B only: Patients with CNS metastases or leptomeningeal carcinomatosis are excluded.\n\* Treatment with prohibited medications less than or equal to 14 days prior to treatment with rociletinib\n\* Patients who are currently receiving treatment with any medications that have the potential to prolong the QT interval and the treatment cannot be either discontinued or switched to a different medication before starting rociletinib\n\* Prior treatment with rociletinib, or other drugs that target T790M positive mutant EGFR with sparing of wild type EGFR\n\* Any of the following cardiac abnormalities or history\n\* Clinically significant abnormal 12-lead ECG, QT interval corrected using Fridericia's method (QTCF) greater than 450 msec\n\* Inability to measure QT interval on ECG\n\* Personal or family history of long QT syndrome\n\* Implantable pacemaker or implantable cardioverter defibrillator\n\* Resting bradycardia less than 55 beats/min\n\* Non-study related surgical procedures less than or equal to 7 days prior to administration of rociletinib. In all cases, the patient must be sufficiently recovered and stable before treatment administration\n\* Females who are pregnant or breastfeeding\n\* Refusal to use adequate contraception for fertile patients (females and males) while on treatment and for 12 weeks after the last dose of rociletinib\n\* Presence of any serious or unstable concomitant systemic disorder incompatible with the clinical study\n\* Any other reason the investigator considers the patient should not participate in the study",  
 "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:  
A patient with \*just\* an EGFR gene mutation might not be eligible. They need to meet \*all\* of the following inclusion criteria and \*none\* of the exclusion criteria:  
  
\*\*Key Inclusion Criteria Related to EGFR Mutation:\*\*  
  
\* \*\*Specific EGFR Mutation Type:\*\* The patient must have 1 or more EGFR mutations \*excluding\* exon 20 insertion. This is crucial. If the patient has an exon 20 insertion mutation, they are \*excluded\*. They also must have documentation confirming the presence of the T790M mutation (Cohort A) or the presence/absence of the T790M mutation (Cohort B).  
\* \*\*Progression on EGFR TKI:\*\* The patient must have experienced disease progression while being treated with a first-line single-agent EGFR tyrosine kinase inhibitor (TKI).  
  
\*\*Other Important Inclusion Criteria:\*\*  
  
\* \*\*Metastatic/Unresectable NSCLC:\*\* The patient must have histologically or cytologically confirmed metastatic or unresectable locally advanced non-small cell lung cancer (NSCLC).  
\* \*\*Prior Treatment:\*\* Limited prior treatment with chemotherapy.  
\* \*\*Performance Status:\*\* ECOG performance status of 0 to 1.  
  
\*\*Key Exclusion Criteria Related to EGFR:\*\*  
  
\* \*\*Exon 20 Insertion:\*\* Explicitly excluded.  
  
Therefore, simply having \*any\* EGFR mutation is not enough. The specific type of mutation matters greatly for this trial. The patient must have a qualifying EGFR mutation (not exon 20 insertion) \*and\* T790M positive (or unknown in Cohort B) and have progressed on a first-line EGFR TKI therapy.