# Clinical Trials Data EGFR - Document 35

# Expanded Access Study of Afatinib in Treatment-naive or Chemotherapy Pre-treated Patients With Non-small Cell Lung Cancer (NSCLC)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01931306

"eligibilityCriteria": "Inclusion criteria:\n\n1. locally advanced or metastatic Non-Small Cell Lung Cancer\n2. Epidermal Growth Factor Receptor mutation positive result per the institution's testing methodology. Any type of EGFR mutation allowed\n3. Treatment na\u00efve or patients who have received one line of chemotherapy, chemotherapy include neo adjuvant and adjuvant chemotherapy within 1 year from enrolment\n4. male or female patients age more than 18 years\n5. Adequate organ function, defined as all of the following:\n\n 1. Absolute Neutrophil Count over 1500 per mm3. ANC over 1000 per mm3 may be considered in special circumstances such as benign cyclical neutropenia as judged by the investigator and in discussion with the sponsor.\n 2. Platelet count more than 75,000 per mm3\n 3. Serum creatinine below 1.5 times of the upper limit of normal\n 4. Total Bilirubin below 1.5 times upper limit of institutional normal. Patients with Gilbert's syndrome total bilirubin must be below 4 times institutional upper limit of normal.\n 5. Aspartate Amino Transferase or Alanine Amino Transferase below three times the upper limit of normal, if related to liver metastases below five times ULN.\n6. ECOG score between 0 - 2\n7. written informed consent by patient or guardian prior to admission into the trial that is consistent with International Conference on Harmonisation - Good Clinical Practice guidelines and local law.\n\nExclusion criteria:\n\n1. prior treatment with an EGFR tyrosine kinase inhibitor\n2. hormonal anti-cancer treatment within 2 weeks prior to start of trial treatment ,continued use of anti androgens and or gonadorelin analogues for treatment of prostate cancer permitted\n3. radiotherapy within 14 days prior to drug administration, except as follows:\n\n 1. Palliative radiation to organs other than chest may be allowed up to 2 weeks prior to drug administration, and\n 2. Single dose palliative treatment for symptomatic metastasis outside above allowance to be discussed with sponsor prior to enrolling.\n4. major surgery within 4 weeks before starting trial treatment or scheduled for surgery during the projected course of the trial\n5. known hypersensitivity to afatinib or any of its excipients\n6. history or presence of clinically relevant cardiovascular abnormalities such as uncontrolled hypertension, congestive heart failure New York Heart Association classification of over 3, unstable angina or poorly controlled arrhythmia as determined by the investigator. Myocardial infarction within 6 months prior to starting trial treatment.\n7. Women of Child-Bearing Potential and men who are able to father a child, unwilling to use adequate contraception prior to trial entry, for the duration of trial participation and for at least 2 weeks after treatment has ended.\n8. childbearing potential who:\n\n 1. are nursing or\n 2. are pregnant or\n 3. are not using an acceptable method of birth control, or do not plan to continue using this method throughout the trial and,or do not agree to submit to pregnancy testing required by this protocol\n9. any history of or concomitant condition that, in the opinion of the investigator, would compromise the patient's ability to comply with the trial or interfere with the evaluation of safety for the trial drug\n10. previous or concomitant malignancies at other sites, except effectively treated non-melanoma skin cancers, carcinoma in situ of the cervix, ductal carcinoma in situ or effectively treated malignancy that has been in remission for more than 3 years and is considered to be cured.\n11. requiring treatment with any of the prohibited concomitant medications that can not be stopped for the duration of trial participation\n12. known pre-existing interstitial lung disease\n13. presence of poorly controlled gastrointestinal disorders that could affect the absorption of the trial drug\n14. active hepatitis B infection, active Hepatitis C infection\n15. meningeal carcinomatosis\n16. symptomatic brain metastases, patients with asymptomatic brain metastases, who were previously treated, are eligible provided they have had Stable Disease for at least 4 weeks on stable doses of medication",  
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 "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 an EGFR gene mutation \*could\* be eligible for this trial, provided they also meet \*all\* of the other inclusion criteria and \*none\* of the exclusion criteria. The presence of the EGFR mutation is just one requirement.  
  
Specifically, having the EGFR mutation satisfies inclusion criterion #2. However, the patient must also:  
  
\* Have locally advanced or metastatic Non-Small Cell Lung Cancer (inclusion #1)  
\* Be treatment naive or have received only one line of chemotherapy (inclusion #3)  
\* Be over 18 (inclusion #4)  
\* Have adequate organ function as defined (inclusion #5)  
\* Have an ECOG score between 0-2 (inclusion #6)  
\* Provide informed consent (inclusion #7)  
  
\*And\* they must \*not\* have any of the exclusion criteria (1-16). A key exclusion is prior treatment with an EGFR tyrosine kinase inhibitor (exclusion #1). This is important because this trial likely involves an EGFR TKI.