# Clinical Trials Data EGFR - Document 21

# A Study of Intermittent, High-dose Afatinib to Determine the Maximal Tolerated Dose and Assess Activity of This Dose Against Non-small Cell Lung Cancer With T790M Mutations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01647711

"eligibilityCriteria": "Inclusion criteria:\n\nPart A only:\n\n1. Patients with histologically confirmed advanced solid tumours that are metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective. Patients who refuse standard therapy are also eligible.\n\n Part B only:\n2. Pathologically confirmed diagnosis of Stage IV (M1a or b) non-small cell lung cancer\n3. Documented Epidermal Growth Factor Receptor (EGFR) T790M mutation\n4. Progression of disease on a reversible tyrosine kinase inhibitor within 30 days of starting study drug. Loss of exposure to prior EGFR TKI should not be \\>30 days; any procedural delay in confirmation of progression is to be discussed with the BI Clinical Monitor.\n\n Parts A and B:\n5. Evaluable disease by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1\n6. Age \\>/= to 18 years\n7. Eastern Cooperative Group (ECOG) performance status 0-1\n8. Adequate organ function\n9. Recovered from any previous therapy-related toxicity to \\</= to Grade 1 at study entry (except for stable sensory neuropathy \\</= Grade 2 and alopecia)\n10. Written informed consent\n11. Ability to take oral medication\n\nExclusion criteria:\n\nParts A and B:\n\n1. Chemotherapy, biological therapy, or investigational agents (except erlotinib or gefitinib) within 4 weeks prior to the start of study treatment\n2. Hormonal treatment within 2 weeks prior to the start of study treatment (continued use of anti-androgens and/or gonadorelin analogues for treatment of prostate cancer is permitted)\n3. Radiotherapy within two weeks prior to the start of study treatment (except palliative radiotherapy given for symptom control)\n4. Less than 3 days from prior treatment with gefitinib or erlotinib. Patients with adverse events related to gefitinib or erlotinib must recover to Grade 1 or less to be eligible.\n5. Major surgery within 4 weeks before starting study treatment or scheduled for surgery during the projected course of the study\n6. Known hypersensitivity to afatinib or the excipients of any of the trial drugs\n7. History or presence of clinically relevant cardiovascular abnormalities such as uncontrolled hypertension, congestive heart failure New York Heart Association classification of 3, unstable angina or poorly controlled arrhythmia as determined by the investigator. Myocardial infarction within 6 months prior to starting study treatment\n8. Women of childbearing potential and men who are able to father a child, unwilling to be abstinent or use adequate contraception prior to study entry, for the duration of study participation and for at least 2 months after treatment has ended.\n9. Female patients of childbearing potential who are nursing; are pregnant; are not using an acceptable method of birth control, or do not plan to continue using this method throughout the study; and do not agree to submit to pregnancy testing required by this protocol\n10. Any history of or concomitant condition that, in the opinion of the investigator, would compromise the patient's ability to comply with the study or interfere with the evaluation of the efficacy and safety of the test drug\n11. 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\n12. Required treatment with any of the prohibited medications listed in this protocol that cannot be stopped for the duration of trial participation\n13. Known pre-existing Interstitial Lung Disease\n14. Any history or presence of poorly controlled gastrointestinal disorders that could affect the absorption of the study drug (for example, Crohn's disease, ulcerative colitis, chronic diarrhea, malabsorption) in the opinion of the investigator\n15. Active hepatitis B infection (defined as the presence of Hepatitis B DNA), active hepatitis C infection (defined as the presence of Hepatitis C RNA) and/or known Human Immunodeficiency Virus carrier\n16. Prior participation in a blinded afatinib clinical study, unless permission to unblind was granted in consultation with the Clinical Monitor of the blinded study\n17. Meningeal carcinomatosis\n18. Patients with brain or subdural metastases are not eligible, unless they have completed local therapy and have discontinued use of corticosteroids or have been on stable doses of corticosteroids for at least 4 weeks before starting study treatment. Any symptoms attributed to brain metastases must be stable for at least 4 weeks before starting study treatment\n19. QTc interval \\> 0.47 seconds as measured during screening procedures",  
 "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 would \*\*not\*\* automatically be eligible for this trial. They would need to meet \*all\* of the following criteria from Part B:  
  
\* \*\*Stage IV (M1a or b) non-small cell lung cancer:\*\* Having an EGFR mutation isn't enough; it must be in the context of this specific type and stage of lung cancer.  
\* \*\*EGFR T790M mutation:\*\* The trial specifically requires this particular EGFR mutation. Just having \*any\* EGFR mutation is not sufficient.  
\* \*\*Progression of disease on a reversible tyrosine kinase inhibitor within 30 days:\*\* The patient must have already tried and failed treatment with a specific type of drug (TKI) recently.  
  
In addition to these Part B criteria, the patient would also have to meet all of the criteria listed under "Parts A and B," including adequate organ function, performance status, and no conflicting medications or conditions.