# Clinical Trials Data EGFR - Document 30

# Erlotinib Hydrochloride With or Without Bevacizumab in Treating Patients With Stage IV Non-small Cell Lung Cancer With Epidermal Growth Factor Receptor Mutations

## Clinical Trial: https://clinicaltrials.gov/study/NCT01532089

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Histologic documentation of primary lung carcinoma, non-squamous histology with activating epidermal growth factor receptor (defined as deletion 19 or exon 21 L858R mutation); Note: EGFR mutation testing must be performed at a Clinical Laboratory Improvement Amendments (CLIA) certified lab; either institutional or through a commercial laboratory (e.g. Genzyme, Response Genetics, etc); the laboratory report from the commercial laboratories report the specific mutations detected, and the method of detecting the exon 19 and exon 21 L858R point mutations must be available\n\* Stage IV disease according to the 7th Edition of the American Joint Committee on Cancer staging system\n\* Measurable disease\n\* Life expectancy of \\>= 12 months\n\* Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1\n\* Absolute neutrophil count (ANC) \\>= 1,500/mm\\^3 obtained =\\< 14 days prior to randomization\n\* Platelet count \\>= 100,000/mm\\^3 obtained =\\< 14 days prior to randomization\n\* Hemoglobin \\>= 9.0 g/dL obtained =\\< 14 days prior to randomization\n\* Total bilirubin =\\< 1.5 x upper limit of normal (ULN) obtained =\\< 14 days prior to randomization\n\* Serum glutamic oxaloacetic transaminase (SGOT) (aspartate aminotransferase \\[AST\\]) and serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase \\[ALT\\]) =\\< 2.5 x ULN in patients without liver or bone metastases; \\< 5 x ULN in patients with liver or bone metastases obtained =\\< 14 days prior to randomization\n\* Cockcroft-Gault calculated creatinine clearance of \\>= 45 ml/min or creatinine =\\< 1.5 x ULN obtained =\\< 14 days prior to randomization\n\* Urine dipstick proteinuria \\< 2+ or urine protein/creatinine (UPC) ratio =\\< 1.0 obtained =\\< 14 days prior to randomization\n\n \* Note: patients discovered to have \\>= 2 + proteinuria on dipstick urinalysis at baseline should undergo a 24-hour urine collection and must demonstrate =\\< 1 g of protein in 24 hours\n\* Negative pregnancy test done =\\< 7 days prior to randomization, for women of childbearing potential only\n\* Provide informed written consent\n\* Willing to return to Academic and Community Cancer Research United (ACCRU) enrolling institution for follow-up\n\* Willing to provide tissue and blood samples for correlative research purposes\n\nExclusion Criteria:\n\n\* Mixed, non-small cell and small cell tumors or mixed adenosquamous carcinomas with a predominant squamous component\n\* Prior chemotherapy or treatment for metastatic non-small cell lung cancer\n\* Any of the following:\n\n \* Pregnant women\n \* Nursing women\n \* Men or women of childbearing potential who are unwilling to employ adequate contraception\n\* Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens\n\* Immunocompromised patients (other than that related to the use of corticosteroids) including patients known to be human immunodeficiency virus (HIV) positive, per medical doctor (MD) discretion\n\* Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations, or any other medical condition that would limit compliance with study requirements\n\* Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm\n\* Other active malignancy =\\< 3 years prior to randomization; EXCEPTIONS: non melanotic skin cancer or carcinoma-in-situ of the cervix; Note: if there is a history of prior malignancy, they must not be receiving other specific treatment (i.e. hormonal therapy) for their cancer\n\* History of myocardial infarction or other evidence of arterial thrombotic disease (angina), symptomatic congestive heart failure (New York Heart Association \\>= grade 2), unstable angina pectoris, or cardiac arrhythmia; Note: allowed only if patient has no evidence of active disease for at least 6 months prior to randomization\n\* History of cerebral vascular accident (CVA) or transient ischemic attack (TIA) =\\< 6 months prior to randomization\n\* History of bleeding diathesis or coagulopathy\n\* Inadequately controlled hypertension (systolic blood pressure of \\> 150 mmHg or diastolic pressure \\> 100 mmHg on anti-hypertensive medications); Note: history of hypertensive crisis or hypertensive encephalopathy not allowed\n\* Current or recent (=\\< 10 days prior to randomization) use of aspirin (\\> 325 mg/day), clopidogrel (\\> 75 mg/day), or prasugrel (\\> 10 mg/day)\n\* Serious non-healing wound, ulcer, bone fracture, or have undergone a major surgical procedure, open biopsy, or significant traumatic injury =\\< 28 days or core biopsy =\\< 7 days prior to randomization\n\* History of abdominal fistula, gastrointestinal perforation, or intraabdominal abscess =\\< 6 months prior to randomization\n\* Known hypersensitivity to Chinese hamster ovary cell products or other recombinant human antibodies\n\* History of hemoptysis \\>= grade 2 (defined as bright red blood of at least 2.5 mL) =\\< 3 months prior to randomization\n\* Known central nervous system (CNS) disease, except for treated brain metastasis; Note: treatment for brain metastases may include whole brain radiotherapy (WBRT), radiosurgery (RS); gamma knife, linear accelerator (LINAC), or equivalent or a combination as deemed appropriate by the treating physician; patients with CNS metastases treated by neurosurgical resection or brain biopsy performed =\\< 3 months prior to randomization will be excluded; Note: craniotomy or intracranial biopsy site must be adequately healed, free of drainage or cellulitis, and the underlying cranioplasty must appear intact at the time of randomization; study treatment should be initiated \\> 28 days following the last surgical procedure (including biopsy, surgical resection, wound revision, or any other major surgery involving entry into a body cavity)\n\* Significant vascular disease (e.g. aortic aneurysm surgical repair or recent peripheral arterial thrombosis) =\\< 6 months prior to randomization\n\* Radiotherapy to any site for any reason =\\< 14 days prior to randomization\n\* Receiving any medications or substances that are strong or moderate inhibitors of CYP3A4; use of the following strong or moderate inhibitors are prohibited =\\< 7 days prior to randomization:\n\n \* Strong inhibitors of CYP3A4: indinavir (Crixivan), nelfinavir (Viracept), atazanavir (Reyataz), ritonavir (Norvir), clarithromycin (Biaxin, Biaxin XL), itraconazole (Sporanox), ketoconazole (Nizoral), nefazodone (Serzone), saquinavir (Fortovase, Invirase), telithromycin (Ketek)\n \* Moderate inhibitors of CYP3A4: aprepitant (Emend), erythromycin (Erythrocin, E.E.S, Ery-Tab, Eryc, EryPed, PCE, fluconazole (Diflucan), grapefruit juice, verapamil (Calan, Calan SR, Covera-HS, Isoptin SR, Verelan, Verelan PM), diltiazem (Cardizem, Cardizem CD, Cardizem LA, Cardizem SR, Cartia XT, Dilacor XR, Diltia XT, Taztia XT, Tiazac)\n\* Receiving any medications or substances that are strong or moderate inducers of CYP3A4; use of the following inducers are prohibited =\\< 7 days prior to randomization: efavirenz (Sustiva), nevirapine (Viramune), carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Tegretol-XR), modafinil (Provigil), phenobarbital (Luminal), phenytoin (Dilantin, Phenytek), pioglitazone (Actos), rifabutin (Mycobutin), rifampin (Rifadin), St. John?s wort",  
 "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:  
Yes, a patient with an EGFR gene mutation \*could\* be eligible for this trial. The inclusion criteria specifically state: "Histologic documentation of primary lung carcinoma, non-squamous histology with activating epidermal growth factor receptor (defined as deletion 19 or exon 21 L858R mutation)".  
  
However, simply having an EGFR mutation is not enough. The patient must also meet \*all\* of the other inclusion criteria (stage IV lung cancer, measurable disease, good performance status, adequate blood counts, acceptable organ function, etc.) and \*none\* of the exclusion criteria (prior treatment for metastatic NSCLC, other active malignancies, certain cardiac conditions, etc.). Therefore, more information about the specific patient's condition is needed to determine definitive eligibility.