# Clinical Trials Data EGFR - Document 18

# Paclitaxel Albumin-Stabilized Nanoparticle Formulation in Treating Patients With Previously Treated Advanced Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01620190

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Pathologically confirmed non-small cell lung cancer with documented EGFR mutation in tumor deoxyribonucleic acid (DNA) or complete/partial response to first line EGFR tyrosine kinase inhibitors with \\> or = to 6 months duration of response in patients who do not have a confirmed EGFR mutation\n\* At least one site of measurable disease as determined by the Investigator, using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria\n\* Progressive disease with radiographic evidence of disease progression per investigator assessment during therapy with an EGFR tyrosine kinase inhibitor in the metastatic setting; patients may continue EGFR inhibitor therapy throughout the screening period until the day prior to nab-paclitaxel treatment initiation\n\* Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2 at the time of informed consent\n\* Platelet count \\>= 100,000/uL\n\* Absolute neutrophil count \\>= 1,500/uL\n\* Hemoglobin \\>= 9 g/dL\n\* Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) = \\< 2.5 times upper limit of normal\n\* Alkaline phosphatase =\\< 2.5 times upper limit of normal, unless bone metastasis is present in the absence of liver metastasis\n\* Bilirubin =\\< 1.5 mg/dL\n\* Creatinine =\\< 1.5 mg/dL\n\* Women of child-bearing potential (WOCP) and sexually active men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry, during treatment and for three months after completing treatment\n\* Negative serum or urine beta-human chorionic gonadotropin (hCG) pregnancy test at screening for patients of childbearing potential\n\* Life expectancy of \\> 12 weeks\n\* Signed and dated informed consent document indicating that the patient has been informed of all the pertinent aspects of the trial prior to enrollment\n\nExclusion Criteria:\n\n\* Prior conventional cytotoxic chemotherapy for metastatic or recurrent disease; prior adjuvant, neoadjuvant or chemoradiotherapy for NSCLC is permitted, provided at least 6 months elapsed prior to documented metastatic recurrence\n\* A single dose of a platinum doublet discontinued due to intolerability without evidence of disease progression is permitted\n\* Patient is \\< 5 years free of another primary malignancy, except: a) if the other malignancy is basal cell carcinoma or cervical carcinoma in situ or b) if the other primary malignancy is not considered clinically significant and is requiring no active intervention\n\* Progressive or symptomatic central nervous system (CNS) metastases; patients with known brain metastasis must have stable disease following treatment with surgery, radiation or both; in addition, they must be off corticosteroids\n\* Radiotherapy within 7 days of study treatment\n\* Peripheral neuropathy grade 2 or greater\n\* Grade III/IV congestive heart failure, as defined by New York Heart Association (NYHA) criteria, or myocardial infarction within 6 months\n\* Any serious or uncontrolled concomitant disorder that, in the opinion of the investigator, would compromise the patient's ability to complete the study\n\* Patient has known chronic liver disease, e.g. diagnosis of chronic active hepatitis or cirrhosis\n\* Major surgery within 21 days of study treatment; minor surgery within 2 weeks of study treatment; placement of vascular access device and biopsies allowed and is not considered major or minor surgery\n\* Patient with any significant history of non-compliance to medical regimens or with inability to grant reliable informed consent\n\* Pregnant or breast feeding females",  
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]

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

Answer:  
Based on the inclusion criteria provided for the clinical trial, a patient with a documented EGFR mutation in tumor DNA would be eligible for the trial, provided they meet all other eligibility requirements. The trial specifically includes patients with non-small cell lung cancer who have a documented EGFR mutation or those who have had a complete/partial response to first-line EGFR tyrosine kinase inhibitors.  
  
However, it's important for patients to also meet all other inclusion and exclusion criteria, such as having a progressive disease with radiographic evidence during therapy with an EGFR tyrosine kinase inhibitor in the metastatic setting, an ECOG performance status of 0, 1, or 2, appropriate blood counts and organ function test results, and not having prior conventional cytotoxic chemotherapy for metastatic disease, among others.  
  
Thus, if the patient with the EGFR gene mutation meets these additional criteria, they would be eligible for the clinical trial.