# Clinical Trials Data EGFR - Document 62

# Preoperative Gefitinib for EGFR Mutant II-IIIa NSCLC (ECTOP-1001)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01833572

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Provision of informed consent\n2. Pathologically confirmed non-small cell lung cancer with EGFR exon 19 deletion or exon 21 L858 mutation.\n3. Clinically or pathologically confirmed stage II-IIIA\n4. Tolerable to complete resection of lung cancer\n5. Male or female aged 18 years and over\n6. Able to comply with the required protocol and follow-up procedures, and able to receive oral medications\n7. ECOG performance status 0-1.\n8. Life expectancy \u226512 weeks.\n9. Adequate hematological function: Absolute neutrophil count (ANC) \u22652.0 x 109/L, and Platelet count \u2265100 x 109/L, and Hemoglobin \u22659 g/dL (may be transfused to maintain or exceed this level).\n10. Adequate liver function: Total bilirubin \u2264 1.5 x upper limit of normal (ULN); Aspartate amino transferase (AST) and alanine amino transferase (ALT) \u2264 2.5 x upper limit of normal (ULN).\n11. Adequate renal function: Serum creatinine \u2264 1.5 x upper limit of normal (ULN), and creatinine clearance\u2265 60 ml/min.\n12. Measurable disease according to the preset criteria .\n\nExclusion Criteria:\n\n1. Known severe hypersensitivity to gefitinib or any of the excipients of this product\n2. Any serious concomitant systemic disorder that, in the opinion of the investigator, would compromise the patient's ability to complete the study\n3. Interstitial lung disease(ILD) or pulmonary fibrosis; impaired pulmonary function (e.g. FEV1 \\<40% predicted value, artery blood gas PaO2\\<60mmHg)\n4. Patients with prior exposure to agents directed at the HER axis (e.g. erlotinib, gefitinib, cetuximab, trastuzumab).\n5. Patients with prior exposure to chemotherapy, irradiation or systemic anti-cancer therapy (e.g. monoclonal antibody therapy) for lung cancer.\n6. Previous or current malignancies of other histologies within the last 5 years with the exception of the following: other malignancies cured by surgery alone and having a continuous disease-free survival of 5 years; cured basal cell carcinoma of the skin and cured in situ carcinoma of the uterine cervix.\n7. Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within six months, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n8. Eye inflammation or eye infection not fully treated or predisposing factor of this.\n9. Evidence of any other disease, neurological or metabolic dysfunction, physical examination or laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or puts the subject at high risk for treatment-related complications.\n10. Patient who has serious active infection\n11. Patients who harbouring exon 20 T790M mutation.\n12. Pregnancy or breast feeding.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
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"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 \*might\* be eligible, but it depends on the \*specific\* EGFR mutation and other factors.  
  
The inclusion criteria specify "EGFR exon 19 deletion or exon 21 L858 mutation." If the patient has one of these \*specific\* mutations, they could be eligible. If they have a different EGFR mutation (like the T790M mutation, which is specifically excluded), they would \*not\* be eligible.  
  
Furthermore, eligibility depends on meeting \*all\* other inclusion criteria (stage of cancer, performance status, organ function, etc.) and \*not\* meeting any of the exclusion criteria (prior treatment, other health conditions, etc.). Simply having the correct EGFR mutation is not enough.