# Clinical Trials Data EGFR - Document 40

# Icotinib Following Chemotherapy Versus Chemotherapy as Adjuvant Therapy in Stage IIA-IIIA NSCLC With EGFR Mutation

## Clinical Trial: https://clinicaltrials.gov/study/NCT01996098

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Written informed consent provided.\n\* Aged 18-75 years.\n\* Had completely resected pathological confirmed stage IIA-IIIA NSCLC.\n\* EGFR activating mutation in exon 19 or 21.\n\* Had completed four cycles of platinum-based adjuvant chemotherapy.\n\* Able to start the investigational therapy within 4 weeks after the completion of four cycles of adjuvant chemotherapy.\n\* ECOG performance status of 0-1.\n\* Had a life expectancy of 12 weeks or more.\n\* Adequate hematological function, adequate liver function and renal function.\n\* Able to comply with the required protocol and follow-up procedures, and able to receive oral medications.\n\* Female patients, except those who are postmenopausal or surgically sterilized, must have a negative pre-study serum or urine pregnancy test.\n\nExclusion Criteria:\n\n\* Had had previous chemotherapy besides four cycles of adjuvant chemotherapy, radiotherapy, or agents directed at the HER axis (e.g. erlotinib, gefitinib, cetuximab, trastuzumab).\n\* Had a history another malignancy in the last 5 years with the exception of cured basal cell carcinoma of the skin, cured in situ carcinoma of the uterine cervix and cured epithelial carcinoma of the bladder.\n\* Any evidence confirmed tumor recurrence before investigational therapy.\n\* Known severe hypersensitivity to icotinib or any of the excipients of this product.\n\* Evidence of clinically active interstitial lung disease.\n\* Eye inflammation not fully controlled or conditions predisposing the subject to this.\n\* Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous 6 months, serious cardiac arrhythmia requiring medication, hepatic, renal, or metabolic disease).\n\* Known human immunodeficiency virus (HIV) infection.\n\* Pregnancy or breast-feeding women.\n\* Ingredients mixed with small cell lung cancer patients.\n\* History of neurologic or psychiatric disorders.",  
 "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, \*\*provided they also meet all other inclusion criteria and do not meet any of the exclusion criteria.\*\* Specifically, the inclusion criteria require an "EGFR activating mutation in exon 19 or 21." Simply having \*any\* EGFR mutation isn't enough; it must be an activating mutation in one of those specific exons. The patient would also need to meet all other requirements (age, cancer stage, prior treatment, etc.) and not be excluded by any of the listed exclusion criteria.