# Clinical Trials Data EGFR - Document 89

# Low Dose Daily Erlotinib in Combination With High Dose Twice Weekly Erlotinib in Patients With EGFR-Mutant Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01967095

"eligibilityCriteria": "Inclusion Criteria:\n\n\* MSKCC pathologically-proven diagnosis locally advanced Stage III not amenable to definitive, curative treatment or Stage IV or recurrent non-small cell lung cancer\n\* Documented presence of EGFR mutation confirmed by MSKCC or a local facility.\n\* No prior treatment with erlotinib, gefitinib, or other EGFR tyrosine kinase inhibitors\n\* Age \u2265 18 years\n\* Measurable (RECIST 1.1) indicator lesion not previously irradiated.\n\* Karnofsky Performance Status \u2265 70%\n\* Ability to take oral medications\n\* A negative serum pregnancy test obtained within 4 weeks prior to the start of treatment in all women of child-bearing potential.\n\* All women of child bearing potential and sexually active men must agree to use adequate methods of birth control throughout the study which includes use of oral contraceptives with an additional barrier methods, double barrier methods, Depo-Provera, permanent sterilization of patient or partner or total abstinence.\n\nExpansion A:\n\n\* brain metastases or leptomeningeal not previously treated with radiation or surgery\n\nExclusion Criteria:\n\n\* Inadequate recovery from any toxicity related to prior treatment (to Grade 2 or baseline).\n\* Inadequate hematologic function defined as ANC \\< 1000 cells/mm\u00b3, Platelet count \\<75,000/mm\u00b3 or Hemoglobin \\<9.0g/dL.\n\* Inadequate hepatic function defined by AST/ALT \\>3x upper limit of normal (ULN), Total bilirubin\\>2x ULN, Alkaline phosphatase \\>3x ULN.\n\* Symptomatic brain metastasis requiring radiation therapy or escalating doses of steroids.\n\* Patients with clinically stable brain metastases or leptomeningeal disease (previously treated or untreated) are eligible. Patients in expansion cohort A must have at least one untreated CNS lesion\n\* Women who are breastfeeding or pregnant.\n\* Any evidence of clinically active interstitial lung disease.",  
 "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: "Documented presence of EGFR mutation confirmed by MSKCC or a local facility."  
  
However, having the EGFR mutation is only \*one\* requirement. The patient must \*also\* meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria to be eligible. For example, they must also have locally advanced Stage III (not amenable to curative treatment), Stage IV, or recurrent non-small cell lung cancer, have no prior treatment with EGFR tyrosine kinase inhibitors, and meet the other listed requirements.