# Clinical Trials Data ERBB2 - Document 18

# Study Of Dacomitinib (PF-00299804) In Advanced NSCLC Patients (Post Chemo Or Select First Line) To Evaluate Prophylactic Intervention On Derm And GI AEs And PRO

## Clinical Trial: https://clinicaltrials.gov/study/NCT01465802

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Advanced Non-Small Cell Lung Cancer (NSCLC).\n\* For Cohort I and Cohort II, advanced NSCLC patients must have received at least one prior regimen of systemic therapy which includes at least one standard chemotherapy for advanced NSCLC and who have failed (ie, progressed or intolerant due to toxicity which precludes further treatment) standard therapy for advanced or metastatic disease. To be considered intolerant to treatment, a patient must have received at least two cycles to be considered previously treated.\n\* For Cohort III, advanced NSCLC patients must not have received prior systemic treatment for their advanced disease and require a known EGFR (HER-1) mutation, HER-2 mutation or HER-2 amplification. Cohort III patients could have received prior adjuvant chemotherapy for Stage I-III disease or combined modality chemotherapy-radiation for Stage IIIA disease is allowed if treatment completed\\>12 months prior to enrollment.\n\* All cohorts, patients must have evidence of disease; however, measurable disease is not required to enroll.\n\* Eastern Cooperative Oncology Group (ECOG) Performance status 0-2\n\* Estimated creatinine clearance \u226515 mL/min.\n\nExclusion Criteria:\n\n\* Prior treatment with an EGFR-targeted or HER-targeted agent (all cohorts).\n\* Chemotherapy, radiotherapy, biological or investigational agents within 2 weeks of baseline disease assessments (all cohorts).\n\* Patients with known diffuse interstitial lung disease (all cohorts).\n\* Investigational therapy as only treatment for advanced NSCLC without administration of an approved chemotherapy for advanced NSCLC (for Cohort I and Cohort II)",  
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"OLDER\_ADULT"  
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Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
A patient with an ERBB2 (HER2) mutation \*could\* be eligible for this trial, but it depends on whether they've received prior systemic treatment for advanced NSCLC:  
  
\* \*\*Eligible for Cohort III:\*\* If the patient has \*not\* received prior systemic treatment for advanced NSCLC, and their ERBB2 mutation is known, they would meet the criteria for Cohort III. Prior adjuvant or combined modality chemo-radiation is allowed under certain conditions.  
  
\* \*\*Not Eligible for Cohort I or II:\*\* If the patient \*has\* received prior systemic treatment for advanced NSCLC (including chemotherapy), they would \*not\* be eligible for Cohorts I or II. These cohorts specifically exclude patients who have received prior EGFR-targeted or HER-targeted therapy. Since ERBB2 is a HER family member, treatment targeting it would exclude the patient from these cohorts.  
  
  
Therefore, the ERBB2 mutation itself does not exclude the patient, but their treatment history is the determining factor.