# 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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"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for the clinical trial, a patient with an ERBB2 (also known as HER-2) gene mutation would be eligible for the trial, specifically for Cohort III. Cohort III of the trial requires patients with advanced NSCLC who have not received prior systemic treatment for their advanced disease, but do have a known EGFR (HER-1) mutation, HER-2 mutation, or HER-2 amplification.   
  
Therefore, if the patient's ERBB2 gene mutation corresponds to a HER-2 mutation, they would satisfy this requirement of Cohort III, provided they meet all other inclusion and exclusion criteria listed, such as having an ECOG Performance status of 0-2, no prior treatment with EGFR-targeted or HER-targeted agents, and so on.