# Clinical Trials Data EGFR - Document 11

# Treatment With BIBW 2992, Irreversible Inhibitor of EGFR and HER-2 in Non-small Cell Lung Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01542437

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Diagnosis of lung cancer non-small cell (stage IIIB or IV) inoperable, locally advanced, recurrent or metastatic, histologically or cytologically documented.\n\* The patient must present evidence of measurable disease.\n\* 18 years of age or older.\n\* ECOG performance status of 0-2\n\* Life expectancy at least 12 weeks.\n\* lung cancer patients with advanced non-small cell, stage IIIB / IV who have received at least one cycle of systemic chemotherapy standard platinum-based first-or second-line fault has been documented that treatment.\n\* are admissible 3 or more prior chemotherapy regimens. Patients must have recovered from any toxic effects and should have passed at least 2 weeks after the last dose prior to registration (14 days for vinorelbine and other vinca alkaloids or gemcitabine). Patients in the opinion of the investigator are fully recovered from surgery for 4 weeks at least, can also be considered for the study. Patients must have recovered from any severe toxicity (CTC \u2264 1) caused by any previous therapy.\n\* granulocyte count \u2265 1.5x 109 / L and platelet count\\> 100 \u00d7 109 / L.\n\* serum bilirubin should be \u2264 1.5 X ULN\n\* AST and / or ALT \u2264 2 ULN (or \u2264 5 x ULN when clearly attributable to the presence of liver metastases).\n\* Serum creatinine \u2264 1.5 (ULN) or creatinine clearance \u2265 60ml/min\n\* Ability to comply with study procedures and monitoring.\n\* Of all women of childbearing potential should be obtained a negative pregnancy test within 72 hours before the start of therapy.\n\* Patients with reproductive potential must use effective contraception.\n\* Written informed consent (signed) to participate in the study.\n\nExclusion Criteria:\n\n\* Any unstable systemic disease (including active infection, grade 4 hypertension, unstable angina, congestive heart failure, liver disease, renal or metabolic).\n\* Pre-treatment with systemic anti-tumor therapy with EGFR inhibitors (tyrosine kinase inhibitors).\n\* Any other malignancy within the previous 5 years (except for carcinoma in situ of the cervix or skin cancer adequately treated basal cell type).\n\* Excluded patients with brain metastases or spinal cord compression of newly diagnosed and / or have not been definitively treated with surgery and / or radiation, supporting both patients with CNS metastases or spinal cord compression previously diagnosed and treated with evidence of stable disease (clinically stable on imaging studies) for a minimum of 2 months.\n\* Any significant ophthalmologic abnormality, especially severe syndrome of dry eye, keratoconjunctivitis sicca, Sjogren's syndrome, severe keratitis exposure and any other condition that may increase the risk of corneal epithelial damage. We do not recommend the use of contact lenses during the study. The decision to continue with the use of contact lenses should be discussed with the treating oncologist and the patient's ophthalmologist.\n\* Patients unable to take oral medication, requiring intravenous nutrition, which have undergone prior surgical procedures affecting absorption, or who have active peptic ulceration.\n\* lactating women.",  
 "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:  
This trial information \*\*does not explicitly exclude\*\* patients with EGFR mutations. However, a key exclusion criterion is: "\*Pre-treatment with systemic anti-tumor therapy with EGFR inhibitors (tyrosine kinase inhibitors).\*"  
  
Therefore, a patient with an EGFR mutation \*could\* be eligible \*\*if they have not previously been treated with an EGFR inhibitor (TKI).\*\* If they \*have\* received prior TKI treatment, they would be ineligible for this particular trial.