# Clinical Trials Data EGFR - Document 82

# Study With Gefitinib in Combination With Olaparib (AZD2281) Versus Gefitinib Alone

## Clinical Trial: https://clinicaltrials.gov/study/NCT01513174

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Patients age 18 years or more.\n2. Histologically confirmed diagnosis of non-small-cell lung carcinoma.\n3. Stage IV disease, following the Seventh Edition of the American Joint Committee on Cancer (AJCC) Cancer Staging Manual (27).\n4. Tumor tissue available (according to the criterion of the specimen-processing laboratory) for EGFR mutation assessment: to be included in the study patients should present at least one EGFR mutation (exon 19 deletion or L858R with or without T790M).\n5. Evidence of measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) criteria version 1.1.\n6. ECOG score \u2264 2.\n7. Life expectancy of \u2265 3 months.\n8. For the Phase II part of the study, patients should not have received previous treatment with chemotherapy or other agents for advanced disease: chemotherapy is allowed if the initial diagnosis of the patient is limited disease and the patient has received adjuvant or neoadjuvant treatment, as long as a minimum of 6 months has passed since the end of the adjuvant and/or neo-adjuvant chemotherapy. This criterion is not mandatory to patients to be included in the Phase I part of the study (these patients are allowed to have received a prior line of treatment for advanced disease).\n9. Patients with the following hematologic values:\n\n \* Absolute Neutrophil Count (ANC) \u22651.5 x 109/L\n \* Hemoglobin (Hb) \u2265 10 g/dl\n \* Platelets \u2265 100 x 109/L\n10. Patients with the following biochemical values:\n\n \* Bilirubin \u2264 1.5 mg/dL\n \* Aspartate aminotransferase (AST) and Alanine transaminase (ALT) \\< 1.5 upper limit of normality\n \* Creatinine clearance \u2265 60 ml/min.\n11. Patients of childbearing age of either sex must use effective contraceptive methods(barrier methods plus other birth control methods) before entering the study and while participating in the study.\n12. Patients should sign an informed consent form before inclusion in the study that specifies that the clinical trial treatment entails consent for the analysis of biological samples of tumor and blood.\n13. Patients must be available for clinical follow-up.\n\nExclusion Criteria:\n\n1. Patients diagnosed of another neoplasm, with the exception of cervical carcinoma insitu, treated squamous cell carcinoma or superficial bladder tumor (Ta and TIS), or other malignant tumors that have received curative treatment within the last 5 years before inclusion in the study.\n2. Simultaneous participation in any other study involving an investigational medicinal product, or having participated in a study less than 28 days prior to the start of study treatment.\n3. Patients with HIV infection, HCV infection, coronary disease or uncontrolled arrhythmia, uncontrolled cerebrovascular disease and other clinical conditions that, in the judgment of the investigator, contraindicate the patient's participation in the study.\n4. Past medical history of interstitial lung disease (ILD), drug-induced interstitial disease, radiation pneumonitis which required steroid treatment or any evidence of clinically active interstitial lung disease.\n5. Pre-existing idiopathic pulmonary fibrosis evidenced by CT scan at baseline.\n6. Uncontrolled seizures.\n7. Patients considered requiring radiotherapy to the lung at the time of study entry or in the near future.\n8. Known or suspected brain metastases or spinal cord compression, unless treated with surgery and/or radiation and stable without steroid treatment for at least 4 weeks prior to the first dose of study medication.\n9. Patients unable to swallow orally administered medication and patients with gastrointestinal disorders likely to interfere with absorption of the study medication.\n10. Patients who are pregnant or breastfeeding. Women of childbearing potential must have a negative pregnancy test performed within 7 days before the onset of treatment(Appendix 8).\n11. Patients receiving the following classes of inhibitors of CYP3A4 (see Appendix 5 for guidelines and wash out periods):\n\n \* Azole antifungals\n \* Macrolide antibiotics\n \* Protease inhibitors\n12. Concomitant use of known CYP3A4 inducers such as phenytoin, carbamazepine, rifampicin, barbiturates, or St John's Wort.\n13. Major surgery within 2 weeks of starting study treatment; patients must have recovered from any effects of any major surgery.\n14. Significant weight loss (= 10% of body weight) in the 6 weeks before inclusion in the study.\n15. Any condition that is unstable or could endanger the patient's safety and/or the patient's compliance with the study.\n16. Substance abuse or clinical, psychological or social conditions that can undermine the validity of the informed consent or protocol compliance.\n17. Patients who present any contraindication or suspected allergy to the products under investigation in the study. Tablets of gefitinib contain lactose: patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose and galactose malabsorption, will not be included in this trial.\n18. Contraindication for steroid use.\n19. Impossibility to comply with treatment due to cultural or geographic circumstances.",  
 "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, based on the eligibility criteria you provided, a patient with an EGFR gene mutation would be eligible for this clinical trial. The inclusion criteria specifically state in point 4 that to be included in the study, patients should present at least one EGFR mutation, such as an exon 19 deletion or L858R, with or without T790M. This inclusion criterion directly addresses the presence of an EGFR gene mutation as a requirement for eligibility.   
  
Make sure that the patient also meets all the other inclusion criteria and does not meet any of the exclusion criteria listed for full eligibility.