# Clinical Trials Data EGFR - Document 118

# SAFIR02\_Lung - Efficacy of Targeted Drugs Guided by Genomic Profiles in Metastatic NSCLC Patients

## Clinical Trial: https://clinicaltrials.gov/study/NCT02117167

"eligibilityCriteria": "Screening phase:\n\nInclusion Criteria:\n\n\* histologically proven NSCLC\n\* Metastatic relapse or stage IV at diagnosis, or stage IIIb not amenable to surgery or radiotherapy\n\* No EGFR-activating mutation or ALK translocation\n\* primary tumor or metastases that can be biopsied, excluding bone.\n\* Age \\>18 years\n\* WHO Performance Status 0/1\n\* Chemo-na\u00efve patients eligible to a first line platinum-based chemotherapy\n\* No tumor progression observed with the current line of treatment\n\* measurable target lesion or evaluable diseases RECIST\n\nExclusion criteria\n\n\* Spinal cord compression and/or symptomatic or progressive brain metastases\n\* Abnormal coagulation contraindicating biopsy\n\* Inability to swallow\n\* Major problem with intestinal absorption\n\* Any clinically important abnormalities in rhythm, conduction or morphology of resting ECG\n\* Any factors increasing the risk of QTc prolongation or arrhythmic events\n\* Experience of any of the following in the preceding 12 months: coronary artery bypass graft, angioplasty, vascular stent, myocardial infarction, past or current uncontrolled angina pectoris, congestive heart failure NYHA Grade \u22652, torsades de pointes, current uncontrolled hypertension, cardiomyopathy\n\* Past medical history of interstitial lung disease, drug-induced interstitial disease, radiation pneumonitis which requires steroid treatment or any evidence of clinically interstitial lung disease\n\* Previous or current malignancies of other histologies within the last 5 years,\n\* Evidence of severe or uncontrolled systemic disease (active bleeding diatheses, or active Hepatitis B, C and HIV)\n\* Diagnosis of diabetes mellitus type I or II\n\* diagnosis of acne rosacea, severe psoriasis and severe atopic eczema\n\* Prior exposure to anthracyclines or mitoxantrone with cumulative exposure in excess of 360 mg/m\u00b2 for doxorubicin, 720 mg/m\u00b2 for epirubicin, or 72 mg/m\u00b2 for mitoxantrone\n\* History of retinal degenerative disease, eye injury or corneal surgery in the previous 3 months, past history of central serous retinopathy or retinal vein occlusion, intraocular pressure \\>21 mmHg, or uncontrolled glaucoma.\n\* History of hemorrhagic or thrombotic stroke, TIA or other CNS bleeds\n\* Renal disease including glomerulonephritis, nephritic syndrome, Fanconi syndrome, renal tubular acidosis\n\* Patients using drugs that are known potent inhibitors or potent inducers or substrates of cytochrome P450\n\nRandomized phase:\n\nSubstudy 1:\n\nInclusion criteria\n\n\* Patients who received 4 cycles of an induction platinum-based chemotherapy and who have a SD or a PR at randomization\n\* presenting at least one genomic alteration from the predefined list\n\* Age \\> 25 years for patients planned to receive AZD4547\n\* 28-day washout period from chemo prior to randomization and grade \u22641 residual toxicities\n\nExclusion criteria\n\n\* Life expectancy \\<3 months\n\* Disease progression occuring at any time during chemotherapy and before randomization or toxicity that led to the discontinuation of the platinum-based chemotherapy before 4 full cycles have been delivered\n\* Less than 28 days from radiotherapy, less than 2 weeks from palliative radiation\n\* Patients previously treated with a targeted agent in the same class as agents tested in this study\n\* Toxicities of grade \u22652 from any previous anti-cancer therapy\n\* Altered haematopoietic or organ function\n\* Mean resting corrected QT interval (QTc) \\>480msec (or QTcF \\>450 msec) obtained from 3 consecutive ECGs\n\* Left ventricular ejection fraction (LVEF) \\<55% (MUGA scan or Echocardiogram),\n\* Altered ophthalmic conditions confirmed by an ophthalmology specialist for patients likely to be treated with AZD4547 orAZD8931 or Selumetinib\n\* Patients using non-substitutable drugs, that are known to prolong QT interval or induce Torsades de Pointes, when they are supposed to be treated with vandetanib, AZD5363 or AZD8931\n\nSubstudy 2:\n\nInclusion criteria\n\n\* Patients who received 4 cycles of an induction platinum-based chemotherapy and who have a SD or a PR at randomization\n\* Patients not eligible to substudy 1\n\* 28-day washout period from chemo prior to randomization and grade \u22641 residual toxicities\n\nExclusion criteria\n\n\* Life expectancy \\<3 months\n\* Disease progression occuring at any time during chemotherapy and before randomization or toxicity that led to the discontinuation of the platinum-based chemotherapy before 4 full cycles have been delivered\n\* Any previous treatment with a PD1 or PD-L1 inhibitor, including MEDI4736\n\* Toxicities of grade \u22652 from any previous anti-cancer therapy\n\* Altered haematopoietic or organ function\n\* Mean resting QT interval corrected for heart rate (QTc) \u2265470 ms calculated from 3 consecutive ECGs using Bazett's Correction\n\* Current or prior use of immunosuppressive medication within 28 days before the first dose of MEDI4736, with the exceptions of intranasal and inhaled corticosteroids or systemic corticosteroids at physiological doses, which are not to exceed 10 mg/day of prednisone, or an equivalent corticosteroid\n\* Active or prior documented autoimmune disease within the past 2 years NOTE: Subjects with vitiligo, Grave's disease, or psoriasis not requiring systemic treatment (within the past 2 years) are not excluded\n\* History of primary immunodeficiency",  
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 "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:  
No. One of the inclusion criteria for the screening phase is "No EGFR-activating mutation or ALK translocation." A patient \*with\* an EGFR mutation would therefore be excluded.