# Clinical Trials Data EGFR - Document 27

# Study of Nivolumab (BMS-936558) in Combination With Gemcitabine/Cisplatin, Pemetrexed/Cisplatin, Carboplatin/Paclitaxel, Bevacizumab Maintenance, Erlotinib, Ipilimumab or as Monotherapy in Subjects With Stage IIIB/IV Non-small Cell Lung Cancer (NSCLC) (CheckMate 012)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01454102

"eligibilityCriteria": "For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com\n\nInclusion Criteria:\n\n\* Newly diagnosed and confirmed Stage IIIB/IV NSCLC\n\* Previously treated NSCLC with asymptomatic brain metastases (eligible for Arm M) See additional details below\n\* Men and women aged \u226518 years\n\* Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1\n\* Subject must be chemotherapy naive (except Arm D, K, L and M). Prior use of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) is acceptable. For Arms D, K, and L, subjects must be non-progressors within 42 days after completion of first-line treatment with \u22654 cycles of Platinum Doublet chemotherapy with or without Bevacizumab. See below for Arm M\n\* Either a formalin fixed tissue block or a minimum of 10 slides of tumor sample (archived or fresh) must be available for biomarker evaluation (a local pathologist must review for adequacy of sampling)\n\* Life expectancy of at least 3 months\n\* Prior radiotherapy must have been completed at least 2 weeks prior to study entry\n\nFor Arm M:\n\n\* No more than 4 brain metastases\n\* Each brain metastases \u22643 cm in size\n\* No evidence of cerebral edema\n\* Subjects must be free of neurologic symptoms related to metastatic brain lesions and must not have required or received systemic corticosteroids for \u226510 days prior to initiation of study treatment\n\* At least 1 measurable target brain lesion \\>0.5 cm and no larger than 3 cm in diameter and/or 2 measurable brain target lesions \\>0.3 cm\n\* No prior radiation therapy, surgery, or other local therapy for target brain lesions\n\* Must have received at least one prior systemic anticancer therapy for NSCLC\n\nExclusion Criteria:\n\n\* Subjects with symptomatic brain metastases, spinal cord compression, or intractable back pain due to a compressive or destructive mass\n\* Subjects who require emergent use of systemic steroids, emergent surgery and/or radiotherapy\n\* Any active or history of a known autoimmune disease\n\* Subjects with previous malignancies (except non-melanoma skin cancers, in situ bladder cancer, gastric, or colon cancers or cervical cancers/dysplasia, or breast carcinoma in situ) are excluded unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required or anticipated to be required during the study period\n\* History of Grade \u22652 neuropathy\n\* Subjects with interstitial lung disease that is symptomatic or may interfere with the detection or management of suspected drug-related pulmonary toxicity",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
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"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:  
A patient with an EGFR mutation \*could\* be eligible for this trial. The inclusion criteria explicitly state, "Prior use of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) is acceptable." This means having an EGFR mutation and even having been treated with a TKI for it does \*not\* disqualify a patient.  
  
However, eligibility depends on several other factors, including:  
  
\* \*\*Stage of NSCLC:\*\* Must be newly diagnosed Stage IIIB/IV NSCLC OR previously treated NSCLC with asymptomatic brain metastases (specific criteria for Arm M).  
\* \*\*Treatment history:\*\* Being chemotherapy naive is required for most arms of the study, \*except\* Arms D, K, L, and M. Arm M specifically requires prior systemic anticancer therapy.  
\* \*\*Performance status:\*\* ECOG 0 or 1.  
\* \*\*Availability of tissue samples:\*\* Tumor samples must be available for biomarker testing.  
\* \*\*Other inclusion/exclusion criteria:\*\* The patient must meet all other inclusion criteria and \*not\* meet any of the exclusion criteria (e.g., symptomatic brain metastases, active autoimmune disease, history of Grade ≥2 neuropathy).  
  
\*\*In summary:\*\* The presence of an EGFR mutation itself is not a barrier to entry. The patient's overall condition and treatment history will determine their eligibility for a specific arm of the study. They should consult with their oncologist and the study investigators to determine if they are a suitable candidate.