# Clinical Trials Data EGFR - Document 129

# Study of Pyrotinib in Patients With Human Epidermalgrowth Factor Receptor 2 (HER2) Positive Advanced Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01937689

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Aged \u226518 and \u226470 years.\n\* ECOG performance status of 0 to 1.\n\* Life expectancy of more than 12 weeks.\n\* At least one measurable lesion exists.(RECIST 1.1)\n\* Histologically or cytologic confirmed HER2 positive advanced breast cancer which failed prior therapies.\n\* Required laboratory values including following parameters:\n\n \* ANC: \u2265 1.5 x 109/L\n \* Platelet count: \u2265 100 x 109/L\n \* Hemoglobin: \u2265 9.0 g/dL\n \* Total bilirubin: \u2264 1.5 x upper limit of normal, ULN\n \* ALT and AST: \u2264 1.5 x ULN\n \* BUN and creatine clearance rate: \u2265 50 mL/min\n \* LVEF: \u2265 50%\n \* QTcF: \\< 470 ms\n\* Signed informed consent.\n\nExclusion Criteria:\n\n\* Subjects with third space fluid that can not be controled by drainage or other methods.\n\* Steroid treatment for more than 50 days, or in need of long-term use of steroids.\n\* Subjects that are unable to swallow tablets, or dysfunction of gastrointestinal absorption.\n\* Less than 4 weeks from the last radiotherapy,chemotherapy\uff0csurgery\uff0chermone treatment,target therapy, or less than 6 weeks from the nitrosoureas or mitomycin chemotherapy.\n\* Subjects with uncontrolled hypokalemia and hypomagnesemia before study entry.\n\* Subjects who can not interrupt the using of the drugs that may cause QT prolongation during study.\n\* Subjects with intracranial lesions.\n\* Treated or treating with HER2 tyrosine kinase inhibitors (TKIs) before study entry.\n\* Receiving any other antitumor therapy.\n\* Less than 4 weeks from the last clinical trial.\n\* Known history of hypersensitivity to pyrotinib or any of it components.\n\* Ongoing infection (determined by investigator).\n\* History of immunodeficiency, including HIV-positive, suffering from other acquired, congenital immunodeficiency disease, or history of organ transplantation.\n\* Subjects had any heart disease, including: (1) angina; (2) requiring medication or clinically significant arrhythmia; (3) myocardial infarction; (4) heart failure; (5) Any heart diseases judged by investigator as unsuitable to participate in the trial.\n\* Female patients who are pregnancy, lactation or women who are of childbearing potential tested positive in baseline pregnancy test.\n\* Female patients of childbearing age that are reluctant to take effective contraceptive measures throughout the trial period.\n\* Evidence of significant medical illness that in the investigator's judgment will substantially increase the risk associated with the subject's participation in and completion of the study. Examples include, but are not limited to,hypertension, severe diabetes, or thyroid disease.\n\* Alcoholism, smoking (daily \u2265 5 roots) and other bad habits.\n\* Known history of neurological or psychiatric disease, including epilepsy or dementia.",  
 "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:  
Based on the provided eligibility criteria, the clinical trial is specific to patients with advanced HER2-positive breast cancer. The presence or absence of an EGFR gene mutation is not mentioned as a factor in the eligibility criteria. Therefore, having an EGFR gene mutation does not specifically affect eligibility for this trial.  
  
However, the key inclusion criterion is that the patient must have HER2-positive advanced breast cancer. If the patient with an EGFR mutation also has HER2-positive breast cancer and meets all other inclusion criteria, and none of the exclusion criteria apply, they may be eligible to participate in the trial.  
  
Ultimately, confirmation of eligibility would depend on a detailed review of the patient's complete clinical profile in relation to all criteria by the trial investigators.