# Clinical Trials Data ERBB2 - Document 41

# Treatment of Chemotherapy Refractory Human Epidermalgrowth Factor Receptor-2( HER-2) Positive Advanced Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01935843

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Chemotherapy refractory HER-2-positive breast cancer, gastric cancer, non-small cell lung cancer, and chemotherapy resistant or relapsed ovary cancer.\n\* Relapsed patients after anti-HER-2 using antibody or kinase inhibitor therapy.\n\* Patients must be 18 years of age or older.\n\* Patients must have an ECOG (Eastern Cooperative Oncology Group )performance status of 0-2.\n\* Patients must have evidence of adequate bone marrow reserve, hepatic and renal function as evidenced by the following laboratory parameters:\n\nAbsolute neutrophil count greater than 1500/mm3. Platelet count greater than 100,000/mm3. Hemoglobin greater than 10g/dl (patients may receive transfusions to meet this parameter).\n\nTotal bilirubin \\< 1.5 times upper limits of normal. Serum creatinine less than or equal to 1.6 mg/ml or the creatinine clearance must be greater than 70 ml/min/1.73m(2).\n\n\* Seronegative for HIV antibody.\n\* Seronegative for active hepatitis B, and seronegative for hepatitis C antibody.\n\* Patients must be willing to practice birth control during and for four months following treatment.NOTE:women of child-bearing age must have evidence of negative pregnancy test.\n\* Patients must be willing to sign an informed consent.\n\nExclusion Criteria:\n\n\* Patients with life expectancy less than 12 months will be excluded.\n\* Patients with uncontrolled hypertension (\\> 160/95), unstable coronary disease evidenced by uncontrolled arrhythmias, unstable angina, decompensated congestive heart failure (\\> New York Heart Association Class II), or myocardial infarction within 6 months of study will be excluded.\n\* Patients with any of the following pulmonary function abnormalities will be excluded: FEV(forced expiratory volume), \\< 30% predicted; DLCO (diffusing capacity of lung for carbon monoxide) \\< 30% predicted (post-bronchodilator); Oxygen Saturation less than 90% on room air.\n\* Patients with severe liver and kidney dysfunction or consciousness disorders will be excluded.\n\* Pregnant and/or lactating women will be excluded.\n\* Patients with active infections, including HIV, will be excluded, due to unknown effects of the vaccine on lymphoid precursors.\n\* Patients with any type of primary immunodeficiencies will be excluded from the study.\n\* Patients requiring corticosteroids (other than inhaled) will be excluded.\n\* Patients with history of T cell tumors will be excluded.\n\* Patients who are participating or participated any other clinical trials in latest 30 days will be excluded.",  
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 "sex": "ALL",  
 "minimumAge": "18 Years",  
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"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ERBB2 gene mutation be eligible for the clinical trial?

Answer:  
Based on the eligibility criteria provided for the clinical trial, a patient with an ERBB2 (HER-2) gene mutation may be eligible if they meet other specific conditions outlined in the inclusion and exclusion criteria. Here are the key points:  
  
1. \*\*Inclusion Criteria\*\*:  
 - The trial targets patients with HER-2-positive cancers, including breast cancer, gastric cancer, non-small cell lung cancer, and ovarian cancer.  
 - The patient must be chemotherapy refractory or have relapsed after anti-HER-2 therapy using antibodies or kinase inhibitors.  
 - Patients must be 18 years or older and have an ECOG performance status of 0-2.  
 - Adequate bone marrow, hepatic, and renal function is required based on specified laboratory parameters.  
 - Patients must be seronegative for HIV, active hepatitis B, and hepatitis C antibody.  
  
2. \*\*Exclusion Criteria\*\*:  
 - Life expectancy should be greater than 12 months.  
 - Uncontrolled hypertension, unstable coronary disease, or serious pulmonary function abnormalities can lead to exclusion.  
 - Severe liver and kidney dysfunction or consciousness disorders result in exclusion.  
 - Pregnant or lactating women are excluded.  
 - The presence of active infections, corticosteroid needs (other than inhaled), or participation in another clinical trial within the last 30 days can lead to exclusion.  
  
If a patient with an ERBB2 gene mutation has HER-2-positive cancer and meets all the inclusion criteria while not falling under any of the exclusion criteria, they could be eligible for this clinical trial.