# Clinical Trials Data ERBB2 - Document 56

# PAM50 HER2-enriched Phenotype as a Predictor of Response to Dual HER2 Blockade in HER2-positive Early Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01973660

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Written informed consent prior to beginning specific protocol procedures\n\* Untreated invasive breast carcinoma eligible for primary definitive surgery (stage I-IIIA)\n\* Histologically confirmed invasive breast carcinoma, with all of the following characteristics: primary tumor \u22651 cm in largest diameter, cN0-2, No evidence of distant metastasis (M0)\n\* HER2-positive invasive breast cancer by central assessment, defined by ASCO/CAP guidelines\n\* Female patients\n\* Age \u226518 years\n\* ECOG performance status of 0 or 1\n\* Adequate organ function defined as: Absolute neutrophil count (ANC) \u22651.5 \u00d7 109/L, Hemoglobin (Hgb) \u226510 g/dL, Platelets \\>100 000/mm3, Creatinine \u22641.6 mg/dL, ALT and AST \u22642.5 \u00d7 ULN, Alkaline phosphatase \u22645 ULN, Total bilirubin \u22641.5 mg/dL, Baseline LVEF \u226550% measured by echocardiography (ECHO) or Multiple Gate Acquisition (MUGA) scan\n\* Negative \u03b2-HCG pregnancy test (serum) for premenopausal women of reproductive capacity (those who are biologically capable of having children) and for women less than 12 months after the menopause. All subjects who are biologically capable of having children must agree and commit to the use of a reliable method of birth control from 2 weeks before administration of the first dose of investigational product until 28 days after last dose of investigational product\n\* Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule\n\* In the case of multifocal tumor (defined as the presence of two or more tumor foci in the same quadrant of the breast), the largest lesion must be \u2265 1 cm, and \"target lesion\" must be designated for all subsequent tumor assessments. In all tumor foci should be documented HER2 status as positive\n\* Availability of enough tumor sample or possibility to take a new biopsy for PAM50 analysis\n\nExclusion Criteria:\n\n\* Stage III inoperable breast cancer or known metastatic disease\n\* Patients for whom upfront chemotherapy including taxanes and anthracyclines is clinically judged appropriate as optimal neoadjuvant treatment\n\* Prior chemotherapy, radiotherapy or surgery for invasive breast cancer, other than excision of tumor in the contralateral breast, and provided that the patient did not previously receive adjuvant radiotherapy or chemotherapy\n\* Subjects with a concurrently active second malignancy, other than adequately treated non-melanoma skin cancers, in situ melanoma or in situ cervical cancer. Subjects with other non-mammary malignancies must have been disease-free for at least 5 years\n\* Known or suspected hypersensitivity reaction to any investigational or therapeutic compound or their incorporated substances\n\* Concurrent congestive heart failure or LVEF \\<50%\n\* Clinically significant (i.e. active) cardiovascular disease, including cerebrovascular accident (\\<6 months before enrollment), unstable angina pectoris, myocardial infarction \u22646 months before enrollment, uncontrolled hypertension (systolic \\>150 mmHg and/or diastolic \\>100 mmHg) or high-risk uncontrolled arrhythmias\n\* Uncontrolled diabetes mellitus, active peptic ulcer disease or uncontrolled epilepsy\n\* Active uncontrolled infection at the time of enrollment\n\* History of significant comorbidities that, in the judgment of the investigator, may interfere with the conduction of the study, the evaluation of response, or with informed consent\n\* Use of any investigational agent or participation in another therapeutic clinical trial concurrently or in the previous 30 days before the enrollment\n\* Patients who are pregnant or breast-feeding\n\* Women of child-bearing potential who are unable or unwilling to use contraceptive measures\n\* Inability or unwillingness to abide by the study protocol or cooperate fully with the investigator\n\* Malabsorption syndrome, disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel. Subjects with ulcerative colitis are also excluded\n\* Concurrent neoadjuvant cancer therapy (chemotherapy, radiation therapy, immunotherapy, biologic therapy other than the trial therapies)\n\* Concomitant use of CYP3A4 inhibitors or inducers",  
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]

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 information provided, the eligibility for the clinical trial requires the participant to have "HER2-positive invasive breast cancer by central assessment, defined by ASCO/CAP guidelines." This refers to the overexpression or amplification of the HER2 protein (also known as ERBB2) in the breast cancer tissue.   
  
If the patient's ERBB2 gene mutation leads to overexpression or amplification consistent with HER2-positive status as defined by the ASCO/CAP guidelines, then the patient would be eligible for this trial. However, if the ERBB2 mutation does not result in a HER2-positive status, according to the specified guidelines, the patient would not be eligible.   
  
Therefore, in summary, a patient with an ERBB2 mutation would be eligible if this mutation results in HER2-positivity as per the trial's criteria.