# Clinical Trials Data ERBB2 - Document 30

# Vaccine Therapy With or Without Polysaccharide-K in Patients With Stage IV HER2 Positive Breast Cancer Receiving HER2-Targeted Monoclonal Antibody Therapy

## Clinical Trial: https://clinicaltrials.gov/study/NCT01922921

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patients with stage IV HER2+ breast cancer treated to:\n\n \* No evidence of disease (NED), or\n \* Stable bone only disease after definitive therapy\n\* HER2 overexpression by immunohistochemistry (IHC) of 2+ or 3+ in the primary tumor or metastasis; or documented gene amplification by fluorescent in situ hybridization (FISH) analysis; IHC =\\< 2+ must have HER2 gene amplification documented by FISH\n\* Patients must continue HER2-targeted monoclonal antibody therapy dosing per standard of care through the entire study period (one year)\n\n \* HER2-targeted monoclonal antibody therapy is defined as either trastuzumab monotherapy, or trastuzumab and pertuzumab combination therapy administered per standard of care\n\* Patients must be at least 21 days post cytotoxic chemotherapy prior to enrollment\n\* Patients must be at least 28 days post immunosuppressants prior to enrollment\n\* Patients must be at least 28 days from use of any mushroom supplements (examples: turkey tail, reishi, maitake, shiitake) and agree to withhold them for the entire study period (one year)\n\* Patients on bisphosphonates and/or endocrine therapy are eligible\n\* Patients who are having sex that could lead to pregnancy must agree to contraceptive use during the entire study period\n\* Patients must have Zubrod performance status score of =\\< 2\n\* Patients must have recovered from major infections and/or surgical procedures, and in the opinion of the investigator, not have significant active concurrent medical illnesses precluding study treatment\n\* White blood cell (WBC) \\>= 3000/mm\\^3\n\* Hemoglobin (Hgb) \\>= 10 g/dl\n\* Serum creatinine =\\< 2.0 mg/dl or creatinine clearance \\> 60 ml/min\n\* Total bilirubin =\\< 1.5 mg/dl\n\* Serum glutamic oxaloacetic transaminase (SGOT) =\\< 2.5 times the upper limit of normal\n\* Patients must have adequate cardiac function as demonstrated by normal left ventricular ejection fraction (LVEF) \\>= the lower limit of normal for the facility on multi gated acquisition (MUGA) scan or echocardiogram (ECHO) within 3 months of enrollment\n\nExclusion Criteria:\n\n\* Patients with any of the following cardiac conditions:\n\n \* Restrictive cardiomyopathy\n \* Unstable angina within 6 months prior to enrollment\n \* New York Heart Association functional class III-IV heart failure\n \* Symptomatic pericardial effusion\n\* Patients with any contraindication to receiving rhu granulocyte macrophage colony stimulating factor (rhuGM-CSF) based products\n\* Patients with any clinically significant autoimmune disease requiring active treatment\n\* Patients receiving any concurrent immunosuppressants\n\* Patients who are pregnant or breast-feeding\n\* Patients who are simultaneously enrolled in other treatment studies\n\* Patients who have received a previous HER2 breast cancer vaccine\n\* Known hypersensitivity reaction to mushroom products",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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:  
The eligibility criteria mention HER2 status, not specifically ERBB2 mutation. While ERBB2 is the gene that encodes the HER2 protein, the trial specifies HER2 status by IHC or FISH, which measure protein overexpression or gene amplification, respectively. A patient with an ERBB2 mutation \*might\* be eligible \*\*if\*\* they also meet the HER2 overexpression/amplification criteria (IHC 2+ or 3+, or FISH positive if IHC <2+). Simply having the mutation isn't sufficient for enrollment based on this information. They would also need to meet all other inclusion criteria and not have any of the exclusion criteria.