# Clinical Trials Data EGFR - Document 130

# 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 EGFR gene mutation be eligible for the clinical trial?

Answer:  
This trial is for patients with \*\*HER2+\*\* breast cancer. The criteria mention HER2 overexpression and gene amplification. While EGFR mutations and HER2 overexpression can sometimes occur in the same patient, they are distinct. This trial does \*\*not\*\* explicitly include patients based on EGFR mutation status. Therefore, having an EGFR mutation alone would \*\*not\*\* qualify a patient for this trial. They would need to meet the HER2+ criteria outlined.