# Clinical Trials Data ERBB2 - Document 16

# Vaccine Therapy in Treating Patients With Metastatic Solid Tumors

## Clinical Trial: https://clinicaltrials.gov/study/NCT01376505

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Must have histologically confirmed metastatic solid tumor; the malignancy should be considered incurable using standard treatment\n\* Patients are not required to have HER-2 over-expression to be on this study\n\* If the patient has had HER-2 expression measured prior to enrollment, the report alone will be accepted\n\* If the patient has not had HER-2 expression measured prior to enrollment on this study tumor tissue blocks and/or freshly isolated tissue must be available for determination of HER-2 expression\n\* Patients are not required to have epidermal growth factor receptor (EGFR) over-expression to be on this study\n\* If the patient has had EGFR expression measured prior to enrollment, the report alone will be accepted\n\* If the patient has not had EGFR expression measured prior to enrollment on this study tumor tissue blocks and/or freshly isolated tissue must be available for determination of EGFR expression\n\* Patients with prior history of treated brain metastases who are off steroids and have stable metastatic brain disease for at least 3 months are eligible\n\* Patients must be ambulatory with an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2\n\n \* White blood cells \\> 3500/mm\\^3\n \* Platelet count \\> 100,000/mm\\^3\n \* Serum bilirubin \\< 1.5 mg %, regardless of whether patients have liver involvement secondary to tumor\n \* Alanine aminotransferase (ALT) must be \\< 2 times upper limit of normal\n \* Creatinine \\< 1.5 mg/dL or calculated creatinine clearance \\> 60 mL/min\n\* Patients will be tested for reactivity to a panel of four common microbial skin test antigens: candida, trichophyton, intermediate strength purified protein derivative (PPD), and tetanus toxoid; determination of patient eligibility for this trial will proceed independently of these skin test results; patients who have previously been tested for these antigens but were excluded from participation in the trial due to non-reactivity may be considered as eligible provided that all other eligibility criteria are met\n\* Patients must be at least 4 weeks past any prior surgery, cytotoxic, chemotherapy, other immunotherapy, hormonal therapy, or radiation therapy; patients having been treated with monoclonal antibodies may enter the trial after a specified period of time (2 times the mean half life of the agent); patients must have recovered from any toxicity of prior therapy prior to enrolling on study except for neuropathy where patients need to recover to less than grade 2\n\* Women of child-bearing potential must not be pregnant and must have a negative pregnancy test; men and women must agree to practice effective contraception while on this study\n\* Patients must obtain a base line Echocardiogram or multi gated acquisition scan (MUGA) and require the left ventricular ejection fraction to be within normal limits (or 50% or higher)\n\* Ability to understand and the willingness to sign a written informed consent document; the patient must be aware that his/her disease is neoplastic in nature and willingly consent after being informed of the procedure to be followed, the experimental nature of the therapy, alternatives, potential benefits, side-effects, risks, and discomforts\n\nExclusion Criteria:\n\n\* Patients with ICH of 0\n\* Patients on targeted therapies, such as Cycline Dependent Kinase (CDK) 4/6 or mammalian target of rapamycin (mTOR) inhibitors in combination with endocrine therapy.\n\* Patients who are {MVF-HER-2(266-296) and MVF-HER-2 (597-626)} immediate hypersensitivity skin test positive\n\* Patients who have evidence of active infection that requires antibiotic therapy; patients must have been off antibiotic treatment for at least 3 weeks prior to initiating treatment and must be confirmed to be clear of the infection; if patient develops an infection requiring antibiotic treatment while on the treatment portion of the study patients will be treated for the active infection with antibiotics and will resume vaccine treatment when the infection is healed\n\* Patients with known active human immunodeficiency virus (HIV), hepatitis A, hepatitis B, or hepatitis C infection\n\* Patients with serious cardiopulmonary disorders, including congestive heart failure, symptomatic coronary artery disease, serious cardiac arrhythmia, and symptomatic chronic obstructive pulmonary disease or patients with other serious uncontrolled medical diseases\n\* Patients who require or likely to require corticosteroids or other immunosuppressives for intercurrent disease are NOT eligible\n\* Splenectomized patients\n\* Autoimmune diseases including rheumatoid arthritis, systemic lupus erythematosus, scleroderma, polymyositis dermatomyositis, or a vasculitic syndrome\n\* Patients who have developed anaphylactic responses to other vaccines\n\* History of congestive heart failure, coronary artery disease and myocardial infarction; active or unstable cardiovascular disease or cardiac disease requiring drug or device intervention\n\nADDITIONAL KEY ELIGIBILITY CRITERIA FOR EXTENSION \\& EXPANSION COHORT:\n\n\* Histologically documented metastatic or unresectable breast, ovarian and gastrointestinal cancers\n\* Progressive disease after at least one line of standard therapy\n\* Patients must have received or refused first line standard systemic therapy for their metastases (if applicable)\n\* Patients (pancreatic and esophageal cancers) must have received no more than two prior cytotoxic chemotherapy regimens in the last two years after standard therapy. Patients (breast and gastrointestinal cancers) must have received no more than three prior cytotoxic chemotherapy regimens in the last two years after standard therapy.\n\* Measurable disease, defined as \u2265 1 lesions that can be accurately measured in \u2265 1 dimensions as \u2265 20 mm with conventional techniques or as \u2265 10 mm with spiral CT scan\n\* Disease that is amenable to biopsy and be willing to undergo tumor biopsy",  
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"ADULT",  
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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:  
This trial does not explicitly exclude patients with an ERBB2 (also known as HER2) gene mutation. In fact, the inclusion criteria explicitly states: "Patients are \*not\* required to have HER-2 over-expression to be on this study." This implies that patients with various HER2 statuses, including mutations, are potentially eligible.  
  
However, having the mutation doesn't guarantee eligibility. The patient still needs to meet \*all\* other inclusion criteria and \*not\* meet any exclusion criteria. This includes having a histologically confirmed metastatic solid tumor, meeting the lab value requirements, performance status requirements, and not having any of the listed exclusionary conditions.