# Clinical Trials Data ERBB2 - Document 23

# Her2 and TGFBeta Cytotoxic T Cells in Treatment of Her2 Positive Malignancy

## Clinical Trial: https://clinicaltrials.gov/study/NCT00889954

"eligibilityCriteria": "INCLUSION CRITERIA:\n\nThe patient must meet the following eligibility inclusion criteria at the time of PROCUREMENT:\n\n1. Diagnosis of advanced stage\\\* or metastatic HER2-positive cancer (Immunohistochemistry or reverse transcription-polymerase chain reaction (RT-PCR) is used to determine HER2 positivity)\n\n Definitions of Malignancies and Advanced Stages:\n\n Breast \u2265Stage IIIb Colon cancer \u2265Stage IIIb Esophageal cancer \u2265Stage IIIb Gastric carcinoma \u2265Stage IIIb Head and Neck cancer Stage IV Lung cancer \u2265Stage IIIb Pancreatic cancer Stage IV Prostate cancer Stage IV\n\n \\\*it is expected that the majority of patients who will be accrued on the protocol will have one of the HER2-positive malignancies listed in the table. If the patient's malignancy is not listed we will use \u2265 Stage IIIb as the definition of advanced stage disease. If Stage IIIb is not part of the staging system for the individual tumor, Stage IV will be used.\n\n For World Health Organization grade III and IV brain tumors):patients will be eligible, who have recurrent or progressive disease after front line therapy.\n2. Karnofsky/Lansky score of 50 or more\n3. EBV seropositive\n4. Greater than or equal to 3 years old\n5. Informed consent explained to, understood by and signed by patient/guardian. Patient/guardian given copy of informed consent.\n\nThe patient must meet the following eligibility criteria to be included for TREATMENT:\n\n1. Diagnosis of advanced stage\\\* or metastatic HER2-positive cancer with disease progressed after receiving at least one prior systemic therapy. (Immunohistochemistry or RT-PCR is used to determine HER2 positivity) \\\*for definition refer to Table above.\n2. Greater than or equal to 3 years old.\n3. EBV-seropositive\n4. Recovered from the acute toxic effects of all prior chemotherapy at least a week before entering this study.\n5. Normal echocardiogram (Left ventricular ejection fraction (LVEF) has to be with in normal, institutional limits)\n\n5. Life expectancy 6 weeks or more\n\n7. Karnofsky/Lansky score of 50 or more\n\n8. Bilirubin 3x or less, Aspartate aminotransferase (AST) 5x or less, Serum creatinine 2x or less upper limit of normal, Hgb 9.0 g/dl or more, white blood cells greater than 2,000/ul, absolute neutrophil count greater than 1,000/ul, Platelets greater than 100,000/ul\n\n9. Pulse oximetry 90% or more on room air\n\n10. Sexually active patients must be willing to utilize one of the more effective birth control methods for 6 months after the CTL infusion. Male partner should use a condom. Acceptable forms of birth control include: \\\* oral contraceptives (\"the pill\"), \\\* intrauterine devices (IUDs), \\\* contraceptive implants under the skin, or contraceptive injections, \\\* condoms with foam.\n\n11. Available autologous transduced EBV-specific cytotoxic T lymphocytes with 15% or more expression of HER2 CAR determined by flow-cytometry and killing of Her2-positive targets 20% or more in cytotoxicity assay.\n\n12. Informed consent explained to, understood by and signed by patient/guardian. Patient/guardian given copy of informed consent\n\nNote: Patients must also not receive antineoplastic drugs while on this study since they would kill the infused T cells.\n\nEXCLUSION CRITERIA:\n\nAt time of Procurement:\n\n1. Known HIV positivity\n\nAt time of Treatment:\n\n1. Severe intercurrent infection\n2. Known HIV positivity\n3. Pregnant or lactating\n4. History of hypersensitivity reactions to murine protein-containing products",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "3 Years",  
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"CHILD",  
"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:  
This trial requires \*\*HER2-positive\*\* cancer, determined by immunohistochemistry or RT-PCR. An ERBB2 gene mutation is not explicitly mentioned as an inclusion or exclusion criterion. While ERBB2 (also known as HER2) mutations can lead to HER2 overexpression, simply having an ERBB2 mutation doesn't automatically qualify someone. The trial specifically requires HER2 \*positivity\* as determined by the mentioned tests.  
  
Therefore, a patient with an ERBB2 gene mutation would need to undergo immunohistochemistry or RT-PCR testing to confirm HER2 positivity. \*\*Only if these tests confirm HER2-positive status would the patient be eligible.\*\*