# Clinical Trials Data ERBB2 - Document 13

# Her2 Chimeric Antigen Receptor Expressing T Cells in Advanced Sarcoma

## Clinical Trial: https://clinicaltrials.gov/study/NCT00902044

"eligibilityCriteria": "INCLUSION CRITERIA:\n\nProcurement Eligibility:\n\n1. Diagnosis of refractory HER2-positive sarcoma or metastatic HER2-positive osteosarcoma.\n2. Karnofsky/Lansky score of 50 or greater\n3. Informed consent explained to, understood by and signed by patient/guardian. Patient/guardian given copy of informed consent.\n\nTreatment Eligibility:\n\n1. Diagnosis of refractory HER2-positive sarcoma or metastatic HER2-positive sarcoma with disease progression after receiving at least one prior systemic therapy.\n2. Recovered from acute toxic effects of all prior cytotoxic chemotherapy at least 4 weeks before entering this study. PD1/PDL1 inhibitors will be allowed to continue during treatment if medically indicated.\n3. Normal ECHO (Left ventricular ejection fraction (LVEF) has to be within normal, institutional limits)\n4. Life expectancy 6 weeks or greater\n5. Karnofsky/Lansky score of 50 or greater\n6. Bilirubin 3x or less, AST 3x or less, Serum creatinine 2x upper limit of normal or less, Hgb 7.0 g/dl or greater, WBC greater than 2,000/ul, ANC greater than 1,000/ul, platelets greater than 100,000/ul. Creatinine clearance is needed for patients with creatinine greater than 1.5 times upper limit of normal.\n7. Pulse oximetry of 90% or greater on room air\n8. 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\n9. Available autologous transduced T lymphocytes with 15% or more expression of HER2 CAR as determined by flow-cytometry and killing of HER2-positive targets 20 % or greater in cytotoxicity assay.\n10. Chest radiograph for baseline evaluation of lungs\n11. Informed consent explained to, understood by and signed by patient/guardian. Patient/guardian given copy of informed consent\n\nEXCLUSION CRITERIA:\n\nAt time of Procurement:\n\n1. Known HIV positivity\n2. Severe previous toxicity from cyclophosphamide or fludarabine\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\n5. Severe previous toxicity from cyclophosphamide or fludarabine",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"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:  
The eligibility criteria specify "HER2-positive sarcoma or metastatic HER2-positive osteosarcoma." While ERBB2 is the gene that codes for HER2, simply having an ERBB2 mutation doesn't automatically qualify someone. The patient needs to have a confirmed diagnosis of sarcoma or osteosarcoma, and it must be HER2-positive (meaning HER2 is overexpressed). A genetic test showing an ERBB2 mutation might contribute to a diagnosis of HER2-positive cancer, but it's not the sole determinant. Therefore, based on this information alone, we can't definitively say whether the patient is eligible. More information is needed.