# 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:  
Whether a patient with an ERBB2 gene mutation is eligible for this clinical trial depends on whether the trial is targeting patients with HER2-positive cancers.   
  
The inclusion criteria state that the patient must have "refractory HER2-positive sarcoma" or "metastatic HER2-positive osteosarcoma." HER2 is another name for the protein encoded by the ERBB2 gene. Therefore, a patient with an ERBB2 gene mutation resulting in HER2 overexpression or amplification is likely to be eligible, assuming they meet the other criteria specified.  
  
Here is a summary of the criteria the patient must meet for both procurement and treatment phases:  
  
1. \*\*Diagnosis\*\*: The patient must have a diagnosis of refractory HER2-positive sarcoma or metastatic HER2-positive sarcoma with disease progression after at least one prior systemic treatment.  
2. \*\*Karnofsky/Lansky score\*\*: A score of 50 or greater is required.  
3. \*\*Acute Toxic Effects\*\*: The patient should have recovered from acute toxic effects of any prior chemotherapy at least four weeks before starting.  
4. \*\*Other Medical Criteria\*\*: Normal echocardiogram (LVEF within institutional limits), life expectancy of 6 weeks or more, specific laboratory criteria (bilirubin, AST, serum creatinine, etc.), and a pulse oximetry of 90% or greater on room air.  
5. \*\*Autologous Transduced T Lymphocytes\*\*: Must have available autologous transduced T lymphocytes with specific expression conditions.  
6. \*\*Informed Consent\*\*: Informed consent must be signed and documented.  
  
\*\*Exclusion Criteria\*\*:  
  
- HIV positivity  
- Severe infections  
- Pregnancy or lactation  
- Severe hypersensitivity to certain drugs or proteins  
- Severe toxicity from specific prior treatments  
  
If the patient with the ERBB2 mutation fits the HER2-positive requirement and meets all the additional criteria without any exclusions, they would be eligible for the clinical trial. It is important to consult with the trial's medical team to confirm eligibility based on these detailed criteria.