# Clinical Trials Data ERBB2 - Document 6

# CMV-specific Cytotoxic T Lymphocytes Expressing CAR Targeting HER2 in Patients With GBM

## Clinical Trial: https://clinicaltrials.gov/study/NCT01109095

"eligibilityCriteria": "INCLUSION CRITERIA:\n\n\* Histopathological verification of glioblastoma multiforme (GBM: WHO grade IV) with recurrent or progressive disease after front line therapy.\n\* HER2 positive GBM\n\* CMV seropositive\n\* Normal ECHO (Left ventricular ejection fraction (LVEF) has to be with in normal, institutional limits)\n\* Life expectancy 6 weeks or greater\n\* Karnofsky/Lansky score 50 or greater\n\* Patient or parent/guardian capable of providing informed consent\n\* Bilirubin 3x or less than normal, AST 5x or less than normal, creatinine 2x normal or less for age and Hgb 9.0 g/dl or more; WBC greater than 2,000/ul; ANC greater than 1,000/ul; platelets greater than 100,000/ul\n\* Pulse oximetry 90% or more on room air\n\* Sexually active patients must be willing to utilize one of the more effective birth control methods for 6 months after the CTL infusion. The male partner should use a condom.\n\* Available autologous HER2.CAR-transduced CMV-specific cytotoxic T lymphocytes with 15% or greater expression of HER2.CAR determined by flow-cytometry and killing of HER2-positive targets 20% or more in cytotoxicity assay.\n\* Recovered from the acute toxic effects of all prior chemotherapy at least 4 weeks before entering this study. One exception is Temozolomide(TMZ), an alkylation agent used as a radiosensitizer and adjuvant chemotherapeutic agent for GBM. Due to the extremely short half life of TMZ, patients will be allowed to continue receiving it up to two days prior to cell infusion and cannot restart until six weeks after the infusion.\n\nEXCLUSION CRITERIA:\n\n\* Severe intercurrent infection\n\* Known HIV positivity\n\* Pregnant or lactating\n\* History of hypersensitivity reactions to murine protein-containing products",  
 "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:  
Based on the eligibility criteria provided, a patient with an ERBB2 gene mutation would not specifically be excluded from the trial based on that mutation alone. However, the inclusion criteria specify that the patient must have "HER2 positive GBM." The ERBB2 gene encodes the HER2 protein, so if the mutation results in increased HER2 expression or activity, the patient could potentially meet this criterion. It's important to determine if the mutation results in HER2 positivity to assess eligibility.  
  
Additionally, the other criteria must also be met, such as CMV seropositivity, normal echocardiogram results, a life expectancy of 6 weeks or greater, and several other lab-based and clinical requirements.  
  
Overall, as long as the patient with the ERBB2 mutation qualifies as having HER2 positive GBM and meets all other clinical trial eligibility criteria, they would be eligible for the trial. It is recommended to discuss with the clinical trial coordinators to clarify specific requirements concerning the ERBB2 mutation and HER2 status.