# 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:  
The eligibility criteria specifies "HER2 positive GBM". ERBB2 is the gene that encodes the HER2 protein. Therefore, a patient with an ERBB2 gene mutation that leads to HER2 overexpression (making them HER2 positive) \*would\* be eligible, assuming they also meet all the other inclusion criteria and don't have any of the exclusion criteria. A mutation in ERBB2 that \*doesn't\* result in HER2 overexpression would likely make them ineligible.