# Clinical Trials Data ERBB2 - Document 7

# A Study of Trastuzumab in Combination With TS-ONE & Cisplatin in First-line Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Advanced Gastric Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01228045

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Patients with histologically proved adenocarcinoma of advanced gastric cancer.\n2. Patients who have HER2-positive cancer confirmed with IHC and/or FISH.\n3. Patients with proved presence of measurable (RECIST criteria) lesions within 28 days before enrollment.\n4. Patients without prior treatment (ex. radiotherapy, chemotherapy, hormonal therapy): Patients who completed adjuvant chemotherapy more than 180 days before may be enrolled but those who received TS-ONE or cisplatin shall be excluded.\n5. Patients with the following function of bone marrow, liver and kidney based on the laboratory tests measured within 14 days before enrollment. Hemoglobin \\>= 8.0 g/dL leukocytes \\>=3,000/mcL absolute neutrophil count \\>=1,500/mcL platelets \\>=100,000/mcL total bilirubin within normal institutional limits AST(SGOT)/ALT(SGPT)=\\<2.5 X institutional upper limit of normal ALP \\< twice of the upper limit of normal, creatinine within normal institutional limits or creatinine clearance \\>=60 mL/min for patients with creatinine levels above institutional normal (When AST(GOT), ALT(GPT) and ALP do not satisfy the conditions above and these values are considered to be caused by cancer, the decision is based on the discretion of investigators or co-investigators) Creatinine clearance can be estimated using Cockcroft-Gault formula man: Ccr (mL/min) = body weight (kg) x (140 - age)/(72 x serum creatinine (mg/dL)), woman: Ccr = male Ccr x 0.85\\].\n6. ECOG performance status =\\<2 (Karnofsky \\>60%; see Appendix A).\n7. Patients who are expected to survive more than 3 months after enrollment.\n8. Age \\>= 21.\n9. Patients of adequate oral intake.\n10. Patients who underwent electrocardiography within 28 days before enrollment.\\\\\n11. Patients who give written informed consent for additional endoscopy to obtain fresh frozen tissue biopsies for translational studies at 2 time points pre-1st cycle of chemotherapy and at progression.\n12. Patients who give written informed consent for enrollment into trial.\n\nExclusion Criteria:\n\n1. Patients for whom TS-ONE or cisplatin or trastuzumab is contraindicated.\n2. History of allergic reactions attributed to compounds of similar chemical or biologic composition to TS-ONE, cisplatin and trastuzumab.\n3. Patients receiving any other investigational agents.\n4. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.\n5. Baseline heart function LVEF (Left Ventricular Ejection Fraction) \\< 50%.\n6. Patients with serious (ex. inpatient care is needed) complications (ex. intestinal paralysis, intestinal occlusion, interstitial pneumonia or pulmonary fibrosis, poorly-controlled diabetes, renal failure or hepatic cirrhosis).\n7. Patients with massive ascites (moderate or higher, beyond the pelvic cavity and retention on the anterior surface of the liver on CT) or pleural effusion retention.\n8. Patients with extensive bone metastasis.\n9. Patients with known brain metastases.\n10. Patients with fresh bleeding from the digestive tract which needs repeated blood transfusion.\n11. Patients with diarrhea (4 or more times per day or watery diarrhea).\n12. Patients with simultaneously active multiple cancer.\n13. Pregnant or lactating female.\n14. Patients with reproductive potential who refuse to use an adequate means of contraception (including male patients).\n15. Other patients evaluated to be inadequate to participate in the study by co-investigators.\n16. No informed consent for either treatment regimen or collection of fresh frozen biopsy tissue for translational studies.",  
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 "sex": "ALL",  
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"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 for the clinical trial, a patient with an ERBB2 gene mutation could potentially be eligible, because ERBB2 is also known as HER2. The inclusion criteria specify that patients must have HER2-positive cancer, which involves mutations or amplifications in the ERBB2 gene leading to overexpression of the HER2 protein. Therefore, if the ERBB2 mutation results in HER2 positivity as confirmed by IHC and/or FISH testing, the patient would meet this specific condition.  
  
The patient would need to satisfy all other inclusion criteria and not fall under any of the exclusion criteria to be eligible for the trial. It is important to have confirmation of HER2 positivity through the specified methods and ensure no other disqualifying factors are present.