# Clinical Trials Data ERBB2 - Document 17

# Safety and Efficacy of SNX-5422 in Human Epidermal Growth Factor Receptor 2 (HER2) Positive Cancers

## Clinical Trial: https://clinicaltrials.gov/study/NCT01848756

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Males or non-pregnant, non-breastfeeding females .\n\* Confirmed diagnosis of locally advanced or metastatic breast, esophagogastric, urothelial, or non-small cell lung cancer.\n\* Histological or cytological confirmed carcinoma with HER2 amplification (IHC 3+ or FISH+ (\\>2 HER2:CEP17)).\n\* Subjects with advanced or metastatic breast cancer must have received no more than 5 prior lines of anticancer therapy, including trastuzumab (but excluding hormonal treatments).\n\* Subjects with advanced or metastatic HER2 positive esophagogastric cancer must have received no more than 5 prior lines of anticancer therapy, including trastuzumab.\n\* Subjects with advanced or metastatic, urothelial carcinoma or non-small cell lung cancer must have received at least one, but no more than 5 prior lines of anticancer therapy.\n\* Measurable disease using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1.\n\* Life expectancy of at least 3 months.\n\* Karnofsky performance score \u226570.\n\* Adequate baseline laboratory assessments\n\* Recovered from toxicities of previous anticancer therapy, with the exception of CTCAE grade 1 sensory neuropathy.\n\nExclusion Criteria:\n\n\* Subjects with symptomatic central nervous system (CNS) metastases who are neurologically unstable\n\* Prior treatment with any Hsp90 inhibitor.\n\* Surgery, radiotherapy, or lesion ablative procedure to the only area of measurable disease.\n\* Major surgery within 4 weeks prior to first dose of SNX-5422.\n\* Treatment with chronic immunosuppressants (e.g., cyclosporine following transplantation).\n\* The need for treatment with medications with clinically-relevant metabolism by the cytochrome P450 (CYP) 3A4 isoenzyme within 3 hours before or after administration of SNX-5422.\n\* Screening ECG QTc interval \u2265470 msec for females, \u2265450 msec for males.\n\* At increased risk for developing prolonged QT interval\n\* Patients with chronic diarrhea or with grade 2 or greater diarrhea despite maximal medical management.\n\* Gastrointestinal diseases or conditions that could affect drug absorption, including gastric bypass.\n\* Gastrointestinal diseases that could alter the assessment of safety, including irritable bowel syndrome, ulcerative colitis, Crohn's disease, or hemorrhagic coloproctitis.\n\* History of documented adrenal dysfunction not due to malignancy.\n\* Known seropositive for human immunodeficiency virus (HIV) or hepatitis C virus (HCV).\n\* History of chronic liver disease.\n\* Active hepatitis A or B.\n\* Current alcohol dependence or drug abuse.\n\* Treatment with other anticancer drugs within 28 days or 5 half-lives of anticancer therapy (whichever is shorter), and treatment with any other investigational agent is prohibited from 30 days prior to the first dose of SNX-5422 and throughout the study\n\* Glaucoma, retinitis pigmentosa, macular degeneration, or any retinal changes detected by ophthalmological examination.\n\* Other serious concurrent illness or medical condition.\n\* Psychological, social, familial, or geographical reasons that would hinder or prevent compliance with the requirements of the protocol or compromise the informed consent process.",  
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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 provided for the clinical trial, a key inclusion requirement is that the patient must have "Histological or cytological confirmed carcinoma with HER2 amplification (IHC 3+ or FISH+ (>2 HER2:CEP17))." HER2 is another name for the ERBB2 gene, which encodes the human epidermal growth factor receptor 2.  
  
Thus, if a patient has a confirmed ERBB2 gene mutation that results in HER2 amplification (HER2 positive status as per IHC 3+ or FISH+), they would meet this specific inclusion criterion and would be eligible for the clinical trial, assuming they meet all the other criteria as well. If the mutation does not result in HER2 amplification (HER2 positive status), the patient may not be eligible based solely on that criterion. It is important to clarify whether the patient's mutation leads to the type of HER2 overexpression or amplification described.