# 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:  
This trial requires \*\*HER2 amplification\*\*, specified as IHC 3+ or FISH+ (>2 HER2:CEP17). An ERBB2 gene mutation is \*\*not the same\*\* as HER2 amplification. While ERBB2 is the gene that codes for the HER2 protein, a mutation in the gene doesn't automatically mean amplification. Amplification refers to an increase in the \*number\* of copies of the HER2 gene, leading to overexpression of the HER2 protein. A mutation is a \*change in the sequence\* of the ERBB2 gene. Therefore, based on the information provided, a patient with \*only\* an ERBB2 gene mutation and \*without\* HER2 amplification would \*\*not\*\* be eligible for this trial.