# Clinical Trials Data ERBB2 - Document 29

# Pilot Study to Evaluate Safety & Biological Effects of Orally Administered Reparixin in Early Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01861054

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Female aged \\> 18 years.\n\* Patients with operable breast cancer, with measurable tumors of more than 1 cm in diameter, that are not candidates for neoadjuvant therapy.\n\* Zubrod (Eastern Co-operative Oncology Group \\[ECOG\\]) Performance Status (PS) of 0-1.\n\* No prior treatment by surgery, radiotherapy, hormone therapy e.g. TAMOXIFEN\u00ae or RALOXIFEN\u00ae for prevention or chemotherapy.\n\* Scheduled to undergo definitive local surgery for breast cancer.\n\* Patients must be willing to undergo two mandatory tumor biopsies (pre and post therapy) that are not required for standard care. A sample of tumor tissue removed during surgery will also be collected for analysis.\n\* Patients must be able to swallow and retain oral medication (intact tablet).\n\* Able to undergo all screening assessments outlined in the protocol after giving informed consent.\n\* Adequate organ function (defined by the following parameters):\n\n 1. Serum creatinine \\< 140 \u03bcmol/L or creatinine clearance \\> 60 mL/min.\n 2. Serum hemoglobin \\> 9 g/dL; absolute neutrophil count \\> 1.5 x 109/L; platelets \\> 100 x 109/L.\n 3. Serum bilirubin \\< upper normal limit (UNL).\n 4. Serum alanine aminotransferase (ALT), aspartate aminotransferase (AST) \u2264 UNL; alkaline phosphatase (ALP) \u2264 UNL; albumin within normal limits.\n\* Documented hormone receptor (ER and progesterone receptor) and HER-2- status.\n\* No known hepatitis B virus (unless due to immunization), hepatitis C virus, human immune deficiency virus-I and II positive status.\n\nExclusion Criteria:\n\n\* Male.\n\* Pregnancy or lactation or unwillingness to use two adequate methods of birth control throughout the study and for 30 days after study discontinuation.\n\* Any other breast cancer types including inflammatory form.\n\* Prior surgery to the breast area or primary axillary dissection.\n\* Prior treatment for breast cancer.\n\* Use of an investigational drug within 30 days preceding the first dose of study medication.\n\* Any prior or current cancer, except in situ uterine carcinoma or basocellular cutaneous cancer considered as definitively cured.\n\* Any associated medical condition considered incompatible with the study, e.g. cardiac, renal, medullar, respiratory or hepatic insufficiency.\n\* Neurological or psychiatric disorders which may influence understanding of study and informed consent procedures.\n\* Active or uncontrolled infection.\n\* Malabsorption syndrome, disease significantly affecting gastrointestinal function.\n\* Hypersensitivity to:\n\n 1. ibuprofen or to more than one non-steroidal anti-inflammatory drug;\n 2. medications belonging to the class of sulfonamides, such as sulfamethazine, sulfamethoxazole, sulfasalazine, nimesulide or celecoxib.",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"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 you provided, a patient with an ERBB2 gene mutation would not necessarily be excluded from the trial just because of the mutation. The inclusion criteria mention that the patient must have "documented hormone receptor (ER and progesterone receptor) and HER-2- status," but an ERBB2 mutation is not mentioned as an exclusion criterion.  
  
ERBB2 is another name for HER-2, which means the mutation might affect the HER-2 status of the tumor. However, whether the HER-2 status (positive or negative) affects eligibility is not explicitly stated in the provided criteria.  
  
Therefore, it would require clarification from the trial organizers to determine if a specific HER-2 status (positive or negative) is required for trial eligibility and whether an ERBB2 mutation affects eligibility. But based on the information provided, merely having an ERBB2 mutation does not automatically exclude a patient.