# Clinical Trials Data ERBB2 - Document 58

# Anti-Tumor Immunity Induced by Cryoablation of Invasive Breast Cancers

## Clinical Trial: https://clinicaltrials.gov/study/NCT01856036

"eligibilityCriteria": "Inclusion Criteria:\n\n1. Subjects with an invasive breast cancer 1.5 cm or less\n2. The breast cancer must be of ductal histology, unifocal, estrogen receptor positive and her2/neu negative.\n3. The tumor must be visible by ultrasound and the subject must not have had prior surgical resection of the primary lesion.\n4. A clip marking the breast cancer must have been placed at the time of initial diagnosis or will be placed prior to cryotherapy.\n5. The breast cancer must be amenable to cryoablation (visible by ultrasound and more than 2 mm from skin or chest wall).\n6. Subjects with metastatic disease at diagnosis who elect to have their primary tumor excised are eligible for enrollment.\n7. For subjects with breast implants, the treating physician must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion with not contact or jeopardize the implant.\n8. Subjects must be able to provide consent.\n\nExclusion Criteria:\n\n1. Subjects with breast cancers of lobular histology, with lymph vascular invasion or extensive intraductal component will be excluded.\n2. Subjects with multi-centric or multi-focal breast cancers\n3. Subjects with breast cancers that have invaded skin or have significant skin tethering (assessed clinically).\n4. Subjects receiving chemotherapy within one year or undergoing neoadjuvant chemotherapy are excluded.\n5. Subjects with metastatic disease at diagnosis will be excluded unless they elect definitive surgical therapy for their primary lesion.\n6. Subjects with breast cancers not amenable to cryoablation (lesions not visible by ultrasound, against the chest wall or within 2 mm of skin) will be excluded.\n7. Subjects diagnosed with another malignancy in the preceding 5 years will be excluded.\n8. Subjects diagnosed with simultaneous bilateral breast cancer.\n9. Subjects receiving immunosuppressive therapy within 6 months including oral steroids will be excluded.",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "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 provided inclusion and exclusion criteria for the clinical trial, eligibility is not specifically determined by mutations in the ERBB2 gene. Instead, the trial specifies that the breast cancer must be "her2/neu negative," which typically refers to the HER2 protein overexpression rather than a genomic mutation. However, the alteration in the ERBB2 gene might affect HER2 status if it results in overexpression or amplification, which would be relevant since HER2 is encoded by ERBB2.  
  
Given only the information about an ERBB2 gene mutation, further specifics on the observed HER2 status would be necessary to determine eligibility. If the mutation leads to HER2 negativity as defined in the trial, the patient may still meet that portion of the eligibility criteria. It would be prudent for the investigator to confirm the molecular characterization of the HER2 status concerning trial requirements.