# 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:  
No. Inclusion criteria #2 specifies that the breast cancer must be HER2/neu negative. A patient with an ERBB2 (which is the gene that codes for HER2) mutation would be HER2 positive and therefore ineligible for this trial.