# Clinical Trials Data EGFR - Document 66

# A Study of Abemaciclib (LY2835219) Combined With Fulvestrant in Women With Hormone Receptor Positive HER2 Negative Breast Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT02107703

"description": "EORTC-QLQ-BR23 measured multi-item functional scales for body image, sexual functioning and future perspective and measured single item symptoms scales which assessed systemic therapy side effects, breast symptoms and arm symptoms. For functional scales, scores ranged from 0 to 100 where higher scores represented a better level of functioning. For symptoms scales, scores ranged from 0 to 100 where higher scores represented a greater degree of symptoms. LS Mean value of changing from baseline to short follow up was estimated from the mixed model that was controlled for Treatment, visit, Treatment\\\*Visit and baseline.",  
 "eligibilityCriteria": "Inclusion Criteria\n\n\* Have a diagnosis of HR+, HER2- breast cancer\n\* Have locally advanced disease not amenable to curative treatment by surgery or metastatic disease. In addition, participants must fulfill 1 of the following criteria:\n\n \* relapsed with radiologic evidence of progression while receiving neoadjuvant or adjuvant endocrine therapy, with no subsequent endocrine therapy received following progression\n \* relapsed with radiologic evidence of progression within 1 year from completion of adjuvant endocrine therapy, with no subsequent endocrine therapy received following progression\n \* relapsed with radiologic evidence of progression more than 1 year from completion of adjuvant endocrine therapy and then subsequently relapsed with radiologic evidence of progression after receiving treatment with either an antiestrogen or an aromatase inhibitor as first-line endocrine therapy for metastatic disease. Participants may not have received more than 1 line of endocrine therapy or any prior chemotherapy for metastatic disease\n \* presented de novo with metastatic disease and then relapsed with radiologic evidence of progression after receiving treatment with either an antiestrogen or an aromatase inhibitor as first line endocrine therapy for metastatic disease. Participants may not have received more than 1 line of endocrine therapy or any prior chemotherapy for metastatic disease\n \* for the endocrine na\u00efve cohort: Must not have received prior endocrine therapy in current or prior disease setting\n\* Have postmenopausal status due to either surgical/natural menopause or ovarian suppression (initiated at least 28 days prior to Day 1 of Cycle 1) with a gonadotropin-releasing hormone (GnRH) agonist such as goserelin\n\* Have a negative serum pregnancy test at baseline (within 14 days prior to randomization) and agree to use medically approved precautions to prevent pregnancy during the study and for 12 weeks following the last dose of abemaciclib if postmenopausal status is due to ovarian suppression with a GnRH agonist\n\* Have either measurable disease or nonmeasurable bone only disease\n\* Have a performance status \u22641 on the Eastern Cooperative Oncology Group (ECOG) scale\n\* Have discontinued previous therapies for cancer (including specifically, aromatase inhibitors, anti-estrogens, chemotherapy, radiotherapy, and immunotherapy) for at least 21 days for myelosuppressive agents or 14 days for nonmyelosuppressive agents prior to receiving study drug, and recovered from the acute effects of therapy (until the toxicity resolves to either baseline or at least Grade 1) except for residual alopecia or peripheral neuropathy\n\nExclusion Criteria\n\n\* Are currently receiving an investigational drug in a clinical trial or participating in any other type of medical research judged not to be scientifically or medically compatible with this study\n\* Have visceral crisis, lymphangitic spread, or leptomeningeal carcinomatosis visceral crisis is not the mere presence of visceral metastases but implies severe organ dysfunction as assessed by symptoms and signs, laboratory studies, and rapid progression of the disease\n\* Have clinical evidence or history of central nervous system metastasis\n\* Have received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant, everolimus, or any CDK4/6 inhibitor. For the endocrine na\u00efve cohort: In addition, have received treatment with any prior endocrine therapy\n\* Have received treatment with a drug that has not received regulatory approval for any indication within 14 or 21 days prior to randomization of study drug for a nonmyelosuppressive or myelosuppressive agent, respectively\n\* Have received recent (within 28 days prior to randomization) yellow fever vaccination\n\* Have had major surgery within 14 days prior to randomization of study drug to allow for post-operative healing of the surgical wound and site(s)\n\* Have a personal history within the last 12 months of any of the following conditions: syncope of cardiovascular etiology, ventricular tachycardia, ventricular fibrillation, or sudden cardiac arrest\n\* Have inflammatory breast cancer or a history of any other cancer (except nonmelanoma skin cancer or carcinoma in-situ of the cervix), unless in complete remission with no therapy for a minimum of 3 years\n\* Have received an autologous or allogeneic stem-cell transplant\n\* Have active bacterial or fungal infection, or detectable viral infection\n\* Have initiated bisphosphonates or approved Receptor activator of nuclear factor kappa-B (RANK) ligand targeted agents \\<7 days prior to randomization",  
 "healthyVolunteers": false,  
 "sex": "FEMALE",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]  
 "description": "EORTC-QLQ-BR23 measured multi-item functional scales for body image, sexual functioning and future perspective and measured single item symptoms scales which assessed systemic therapy side effects, breast symptoms and arm symptoms. For functional scales, scores ranged from 0 to 100 where higher scores represented a better level of functioning. For symptoms scales, scores ranged from 0 to 100 where higher scores represented a greater degree of symptoms. LS Mean value of changing from baseline to short follow up was estimated from the mixed model that was controlled for Treatment, visit, Treatment\\\*Visit and baseline.",

Question:  
Based on the following clinical trial information, would a patient with a EGFR gene mutation be eligible for the clinical trial?

Answer:  
This trial is for HR+, HER2- breast cancer. EGFR mutation status is not mentioned in the inclusion or exclusion criteria. Therefore, having an EGFR mutation would \*\*not automatically disqualify\*\* a patient. They would still need to meet all other inclusion criteria and not have any of the exclusion criteria to be eligible.