

N083E-Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer

- This study being conducted to evaluate the safety of adding lapatinib to the T (docetaxel) C (carboplatin) H (trastuzumab) regimen, in anticipation that it may allow the addition of this regimen in the context of the ongoing ALTTO study (N063D)

Major Inclusion Criteria:

- Non-metastatic operable primary invasive adenocarcinoma of the breast fulfilling the following:
 - a. Histologically confirmed;
 - b. Adequately excised¹
 - c. Sentinel lymph node dissection (SLND) and/or axillary lymph node dissection (ALND)
 - d. Node positive patient
- OR
- Node negative patient and determined by physician to be eligible to receive adjuvant trastuzumab
- Baseline LVEF $\geq 50\%$ measured by echocardiography or MUGA scan
- Over expression and/or amplification of HER2 in the invasive component of the primary tumor, according to one of the following definitions [Wolff, 2007].¹
- Adequate hematologic and liver function¹
- Availability of diagnostic tissue and operative and pathology reports from breast cancer diagnosis

¹See protocol for more specific details

Major Exclusion Criteria:

- History of any prior invasive breast cancer
- Current or history (<10 years) of any other malignant neoplasm, except adequately treated basal and squamous cell carcinoma of the skin or carcinoma in situ of the cervix²
- History of any clinical staged T4 tumor, including inflammatory breast cancer
- Prior chemotherapy for any cancer, including the current breast cancer
- Any prior mediastinal irradiation, except internal mammary nodes for the present breast cancer
- Serious cardiac illness or medical conditions including but not limited to²:
 - Documented CHF of any NYHA class or systolic dysfunction (LVEF<50%)
 - High risk uncontrolled arrhythmias²
 - Angina pectoris requiring medication
 - Clinically significant valvular heart disease
 - Poorly controlled HTN²
- Ulcerative colitis, malabsorption syndrome, or any disease affecting gastrointestinal function, history of resection of the stomach or small bowel, or inability to swallow oral medications
- Concomitant use of CYP3A4 inhibitors or inducers²
- ²See protocol for more specific details

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