

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

009/25/2009

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

Prior to discussing this protocol with a patient, call the NCCTG Registration Office (507/284-4130) to see if there is a place available for your patient.

To register a patient, call the NCCTG Registration Office at (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the NCCTG Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

Registration date (date on) (mm/dd/yyyy) ___/___/_____

Patient study ID number (provided at time of Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____	Race (check all that apply)
Gender (check one) ___ Male ___ Female ___ Unknown	___ White
Date of birth (mm/dd/yyyy) ___/___/_____	___ Black or African American
ZIP code _____	___ Native Hawaiian or Other Pacific Islander
Country of Residence _____	___ Asian
	___ American Indian or Alaska Native
	___ Not reported: Patient refused or not available
	___ Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
___ PI (Private Insurance)	___ Not Hispanic or Latino
___ MR (Medicare)	___ Hispanic or Latino
___ MRP (Medicare and Private Insurance)	___ Not reported: Refused or data not available
___ MD (Medicaid)	___ Unknown: Unsure of their ethnicity
___ MM (Medicaid and Medicare)	
___ MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
___ MS (Military Sponsored [including CHAMPUS & TRCARE])	
___ MV (Veterans Sponsored)	
___ SP (Self pay [no insurance])	
___ NP (No means of payment [no insurance])	
___ OTH (Other)	
___ UNK (Unknown)	

Addendum 2 dated September 25, 2009 IRB approved?
 ___ Yes. If Yes, Addendum 2 approval date (mm/dd/yyyy) ___/___/_____

___ No. If No, End form, Addendum 2 IRB approval required.

Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Inclusion Criteria

Yes No NA

Women or men ≥ 18 years of age. Age = _____.	____	____	____
Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1 . ECOG performance status = _____.	____	____	____
Non-metastatic operable primary invasive adenocarcinoma of the breast fulfilling the following:			
a. Histologically confirmed;			
b. Adequately excised. NOTE: Patients who have ‘non-resectable’ deep margin invasion are eligible provided they have had or will receive radiotherapy encompassing the region concerned. NOTE: Patients with histologically documented infiltration of the skin (pT4) are eligible provided they have undergone or will receive radiotherapy encompassing the tumor bed.			
c. Sentinel lymph node dissection (SLND) and/or auxiliary lymph node dissection (ALND)	____	____	____
d. Node positive patient OR Node negative patient and determined by physician to be eligible to receive adjuvant trastuzumab. NOTE: Isolated tumor cells (ITC) are considered pN0 and micrometastases are considered pN1.			
Known hormone receptor status (ER/PgR or ER alone).	____	____	____
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]: - 3+ over expression by IHC ($>30\%$ of invasive tumor cells); - 2+ or 3+ (in 30% or less neoplastic cells) over expression by IHC AND <i>in situ</i> hybridization (FISH/CISH) test demonstrating HER2 gene amplification; - HER2 gene amplification by FISH/CISH (>6 HER2 gene copies per nucleus, or a FISH ratio [HER2 gene copies to chromosome 17 signals] of >2.2). NOTE: Patients with a negative or equivocal overall result (FISH test ratio of <2.2 , <6.0 HER2 gene copies per nucleus) and staining scores of 0, 1+, 2+ or 3+ (in 30% or less neoplastic cells) by IHC are not eligible for participation in the trial.			
The following laboratory values must be obtained ≤ 14 days prior to registration. Earliest laboratory test date ___/___/____; latest laboratory test date ___/___/____. NOTE: These dates pertain to the following labs only.			
• Hemoglobin ≥ 10.0 g/dL. Hemoglobin = _____.	____	____	____
• Absolute neutrophil count (ANC) $\geq 1500/\text{mm}^3$. Absolute neutrophil count (ANC) = _____.	____	____	____
• Platelets $\geq 100,000/\text{mm}^3$. Platelets = _____.	____	____	____
• Serum creatinine ≤ 2.0 x institutional upper limit of normal (ULN) Serum creatinine = _____. ULN = _____.	____	____	____
• AST (SGOT) ≤ 2.5 x ULN. AST (SGOT) = _____. ULN = _____.	____	____	____
• ALT (SGPT) ≤ 2.5 x ULN. ALT (SGPT) = _____. ULN = _____.	____	____	____
• Alkaline phosphatase ≤ 2.5 x ULN. Alkaline phosphatase = _____. ULN = _____.	____	____	____
• Bilirubin ≤ 1.5 x ULN (≤ 2.0 x ULN if known Gilbert’s Syndrome). Is there known Gilbert’s Syndrome? (This question may be answered yes or no). ____ Yes \rightarrow Bilirubin (≤ 2.0 x ULN) = _____. ULN = _____. ____ No \rightarrow Bilirubin (≤ 1.5 x ULN) = _____. ULN = _____.	____	____	____
Negative pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. If not a woman of childbearing potential or male (<i>check NA</i>) If a woman of childbearing potential – Negative pregnancy test date ___/___/____	____	____	____
Availability of diagnostic tissue and operative and pathology reports from breast cancer diagnosis (see Sections 6.0 and 17.0).	____	____	____

All responses in above section must be “Yes” unless specified as “NA.”

Patient study ID number _____

Exclusion Criteria

Yes No NA

Any prior mediastinal irradiation except internal mammary node irradiation for the present breast cancer.	___	___	
Positive or suspicious internal mammary nodes identified by sentinel node technique which have not been irradiated or will not be irradiated, OR Supraclavicular lymph node involvement (confirmed by fine needle aspirate or biopsy).			
Prior use of anti-HER2 therapy for any reason or other prior biologic or immunotherapy for breast cancer.	___	___	
Concurrent anti-cancer treatment, except hormonal therapy or radiotherapy for the present breast cancer.	___	___	
Concurrent anti-cancer treatment in another investigational trial with hormone therapy or immunotherapy unless approved by the Study Chair.	___	___	
Serious cardiac illness or medical conditions including but not confined to: - History of documented congestive heart failure (CHF) (any NYHA class) or systolic dysfunction (LVEF <50%) - High-risk uncontrolled arrhythmias (ventricular tachycardia, high-grade AV-block (2 nd degree or higher), supraventricular arrhythmias which are not adequately rate-controlled) - Angina pectoris requiring antianginal medication - Clinically significant valvular heart disease - Evidence of transmural infarction on ECG - Poorly controlled hypertension (any reading systolic >180 mm Hg or diastolic >100mm Hg)			
Other concurrent serious diseases that may interfere with planned treatment including severe pulmonary conditions/illness.	___	___	
Ulcerative colitis, malabsorption syndrome, any disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel, or inability to swallow oral medication.			
Pregnant or lactating women.	___	___	
Women of childbearing potential and male participants with partners of childbearing potential, including women whose last menstrual period was <1 year ago (unless surgically sterile – hysterectomy and/or ovariectomy) who are unable or unwilling to use adequate contraceptive measures during study treatment.			
Concomitant use of CYP3A4 inhibitors or inducers. (See Appendix V for list of common inhibitors and inducers).	___	___	

All responses in above section must be “No.”

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

Consent form signed and dated. Date of consent ___/___/_____	___	___	
Authorization for use and disclosure of protected health information signed and dated. If not a USA institution (<i>check NA</i>); If a USA institution - Date of authorization ___/___/_____	___	___	___
This protocol has mandatory safety monitoring – sites enrolling first 10 patients must participate in twice monthly conference calls (see Section 16.73).			
Expedited reporting is required for the first 10 patients registered to the trial. In order to assess the adverse event profile of the first 10 patients in a timely manner, the expected CRFs for these patients must be entered <= 14 days after adverse event reporting for Cycle 1 (ie within 14 days of first day of Cycle 2). If site is not able to comply with this requirement, patient may not be registered as one of first 10 patients on trial.			
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.			
Treatment cannot begin prior to registration and must begin ≤14 days after registration.	___	___	

Patient study ID number _____

Registration Check - continued

	Yes	No	NA
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____ NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	___	___	___
Exceptions to the above dates (see Section 4.0): <ul style="list-style-type: none"> Mammography or breast MRI may be completed ≤12 months (360 days) prior to registration Chest Earliest exception test date ___/___/____; latest exception test date ___/___/____. Note: The earliest exception test date must be less than or equal to the latest exception test date.	___	___	___
<ul style="list-style-type: none"> Chest x-ray or chest CT or PET may be completed ≤2 months (60 days) prior to registration. Earliest exception test date ___/___/____; latest exception test date ___/___/____. Note: The earliest exception test date must be less than or equal to the latest exception test date.	___	___	___
All required baseline symptoms must be documented and graded (see Section 10.3).	___	___	___
Study drug availability checked.	___	___	___
Blood draw kit availability checked. (Kit must be available on site for this patient.)	___	___	___

All responses in above section must be “Yes” unless specified as “NA.”

Registration Office will register patients separately to the optional translational research component of this study (see Section 14.0). The following will be recorded: <ul style="list-style-type: none"> Patient has given permission to give blood sample(s) for research testing Patient has given permission to give tissue sample(s) for research testing 	___	___	___
At the time of registration, the following will also be recorded: <ul style="list-style-type: none"> Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat cancer. Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease). Patient has given NCCTG permission to give my sample(s) to outside researchers. 	___	___	___

All responses in above section may be “Yes” or “No”.

Assigned Treatment

___ Arm A: TATER+CBDCA+HERCEP+TYKERB

Person registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (mm/dd/yyyy) ___/___/____