

NORTH CENTRAL CANCER TREATMENT GROUP
Eligibility Checklist

10/30/2009

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N0735: Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

First 6 patients: To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

After the first 6 patients, to register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application

Has the patient ever been on a prior study entered through this Registration Office? Yes No

If yes: Prior study number _____; prior patient study ID number _____

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) _____

Gender (check one) Male Female Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

Zip code _____

Country of Residence _____

Race (check all that apply)

White

Black or African American

Native Hawaiian or Other Pacific Islander

Asian

American Indian or Alaska Native

Not reported: Patient refused or not available

Unknown: Patient unsure

Method of payment (check one)

PI (Private Insurance)

MR (Medicare)

MRP (Medicare and Private Insurance)

MD (Medicaid)

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)

Ethnicity (check one)

Not Hispanic or Latino

Hispanic or Latino

Not reported: Refused or data not available

Unknown: Unsure of their ethnicity

Patient study ID number _____

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

Required Characteristics

Yes No NA

Women or men \geq 18 years of age. Age _____.	___	___	___
Histologically or cytologically diagnosed infiltrating breast cancer with clinical evidence of metastatic disease.	___	___	___
Measurable disease (defined by the presence of at least one measurable lesion per RECIST criteria; see Section 11.0).	___	___	___
May have received one prior adjuvant chemotherapy regimen, and no chemotherapy for metastatic disease. Neoadjuvant chemotherapy is also allowed. Taxane therapy is allowed as adjuvant or neoadjuvant treatment if completed \geq 6 months before study entry.	___	___	___
If patient is HER2+ must have received prior treatment with trastuzumab or have contraindication for trastuzumab. If not HER2+ (<i>check NA</i>).	___	___	___
May have received prior hormonal treatment in either adjuvant or metastatic setting. Unlimited prior hormonal therapy is allowed.	___	___	___
The following laboratory values obtained \leq 15 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____.	___	___	___
NOTE: These dates pertain to the following labs only.	___	___	___
• ANC \geq 1500/mm ³ . ANC = _____.	___	___	___
• PLT \geq 100,000/mm ³ . PLT = _____.	___	___	___
• HgB \geq 9.0 g/dL. HgB = _____.	___	___	___
• AST (SGOT) \leq 2.5 x upper limit of normal (ULN). AST (SGOT) = _____; ULN _____.	___	___	___
• ALT (SGPT) \leq 2.5 x upper limit of normal (ULN). ALT (SGPT) = _____; ULN _____.	___	___	___
• Alkaline phosphatase \leq 2.5 x ULN. Alkaline phosphatase = _____; ULN _____.	___	___	___
• Total bilirubin \leq 1.5 x ULN. Total bilirubin = _____; ULN _____.	___	___	___
• Creatinine \leq 1.5 mg/dL. Creatinine = _____.	___	___	___
• Urine Protein/Creatinine Ration (UPCR) < 1 or Urinalysis <1+ protein. Urine protein = _____.	___	___	___
Patients discovered to have \geq 1+ proteinuria at baseline must undergo a 24-hour urine collection. This collection must be adequate, and must demonstrate <1g of protein/24hr to allow participation in the study.	___	___	___
Negative pregnancy test done \leq 7 days prior to registration, for women of childbearing potential only.	___	___	___
Not a woman of childbearing potential or male (<i>check NA</i>) vs. negative pregnancy test date ___/___/_____.	___	___	___
Life expectancy \geq 12 weeks.	___	___	___
ECOG performance status (PS) 0 or 1. PS = _____.	___	___	___
Ability to complete questionnaire(s) alone or with assistance.	___	___	___

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

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Contraindications

Yes No NA

Any of the following because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential, who are unwilling to employ adequate contraception as determined by the treating physician, while on this study and for 30 days after end of treatment with the study drugs. 	____	____	
Prior chemotherapy for metastatic disease.	____	____	
Major surgery, chemotherapy, or immunologic therapy ≤ 6 weeks prior to registration.	____	____	
Minor surgery (e.g. core biopsy) ≤ 7 days prior to registration. Note: Placement of vascular access device does not require 7 day wait.	____	____	
Neurosurgery ≤ 3 months prior to registration.	____	____	
Evidence of active brain metastasis per MRI or CT, including leptomeningeal involvement. CNS metastasis controlled by prior surgery and/or radiotherapy are allowed. (To be considered controlled, there must be at least 2 months of no symptoms or no evidence of progression prior to study entry.)	____	____	
Only non-measurable disease is defined as all other lesions, including small lesions (longest diameter < 2 cm) and truly non-measurable lesions, which include the following per RECIST criteria dated June 1999 (see Section 11.0 for RECIST criteria): <ul style="list-style-type: none"> • Bone lesions • Leptomeningeal disease • Ascites • Pleural/pericardial effusion • Inflammatory breast disease • Lymphangitis cutis/pulmonis • Abdominal masses that are not confirmed and followed by imaging techniques • Cystic lesions 	____	____	
Pre-existing peripheral neuropathy $> \text{Grade } 1$ (using CTCAE v3.0 criteria).	____	____	
Radiotherapy ≤ 4 weeks prior to registration, except if to a non-target lesion only, or single dose radiation for palliation. Prior radiation to a target lesion(s) is permitted only if there has been clear progression of the lesion since radiation was completed. If patient receives single dose radiation for palliation or radiation to non-target lesion, they may immediately proceed to registration without waiting 4 weeks.	____	____	
Received treatment with any other cytotoxic chemotherapeutic agent or investigational drug ≤ 4 weeks prior to registration.	____	____	
Received treatment with any taxane (docetaxel or paclitaxel) ≤ 6 months prior to registration.	____	____	
Current or recent use (≤ 2 weeks prior to registration) of aspirin, anticoagulants or thrombolytic agents. Exception allowed for one-daily 81 mg aspirin.	____	____	
History of allergy or hypersensitivity to albumin-bound paclitaxel, paclitaxel, gemcitabine, bevacizumab, albumin, drug product excipients, or chemically similar agents.	____	____	
Any Stage III or IV invasive, non-breast malignancy in ≤ 5 years prior to registration.	____	____	
Active other malignancy, excepting non-melanotic skin cancer or carcinoma-in-situ of the cervix. If there is a history of prior malignancy, patient must not be receiving other specific treatment for their cancer.	____	____	
Uncontrolled hypertension (blood pressure [BP] $> 160/90$ mmHg on ≥ 2 occasions at least 5 minutes apart). (Patients who have recently started or adjusted antihypertensive medications are eligible providing that BP is $< 140/90$ mmHg on any new regimen for ≥ 3 different observations in ≥ 14 days.)	____	____	
History of hypertensive crisis (CTCAE Grade 4 Hypertension) or hypertensive encephalopathy.	____	____	
Presence of bleeding diathesis or uncontrolled coagulopathy.	____	____	
Hemoptysis ≤ 6 months prior to registration.	____	____	

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Contraindications continued

	Yes	No
History of abdominal fistula or gastrointestinal perforation ≤6 months prior to registration.	___	___
Serious non-healing wound, ulcer or fracture.	___	___
Arterial or venous thrombosis ≤12 months prior to registration.	___	___
History of cerebrovascular accident.	___	___
Clinically significant cardiac disease (define as congestive heart failure, symptomatic coronary artery disease, unstable angina or cardiac arrhythmias not well controlled with medication) or myocardial infarction ≤12 months prior to registration.	___	___
Currently receiving treatment in a different clinical study in which investigational procedures are performed or investigational therapies are administered. Note: Patient may not enroll in such clinical trials while participating in this study. Exception may be granted for trials related to symptom management (Cancer Control) which do not employ hormonal treatments or treatments that may block the path of the targeted agents used in this trial.	___	___
Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens.	___	___

All responses in above section must be “No” unless specified as “NA.”

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. Non-USA institution only (check NA) vs. Date of authorization ___/___/____.	___	___	___
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 ≤8 days after registration.	___	___	___
Pretreatment tests/procedures must be completed ≤22 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.	___	___	___
All required baseline symptoms must be documented and graded.	___	___	___
Study drug availability checked. (Study drug must be in site pharmacy for this patient prior to registration.)	___	___	___
Blood kit availability check. (Kits are required for this study.) (Site must have a kit on hand for this patient prior to registration.)	___	___	___
Patient QOL booklet availability checked (copies are not acceptable.) (Site must have booklets on hand for this patient prior to registration.)	___	___	___

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

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Registration Check continued

Yes No

Patients should also be enrolled on N0392. (Was It Worth It – QOL study). (NCCTG Protocol N0392 must be open at site and offered to patient.) Patient was offered N0392 and agreed to participation.	
An optional translational research component is available for your patient.	
• 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:	
• Patient has given permission to store and use blood sample(s) for future research of cancer.	____
• Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat other health problems.	____
• Patient has given NCCTG permission to give her/his blood sample(s) to outside researchers.	____
• Patient has given permission to store and use tissue sample(s) for future research of cancer.	____
• Patient has given permission to store and use tissue sample(s) for future research to learn about, prevent, or treat other health problems.	____
• Patient has given NCCTG permission to give her/his tissue sample(s) to outside researchers.	____

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

Assigned Treatment

_____ A) ABRAXANE + GEMZAR + AVASTN

Person registering _____ Signature Registration Office specialist _____ initials

Physician _____ Signature M - D - Y