

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

12/18/2009

Page 1 of 5

N0821: A phase II first-line study of a combination of pemetrexed, carboplatin and bevacizumab in advanced nonsquamous NSCLC evaluating efficacy and tolerability in elderly patients (age  $\geq 70$  yrs) with good performance status (PS  $< 2$ )

**To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.**

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

NCCTG Eligibility Checklist N0821

12/18/2009  
Page 2 of 5

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

≥70 years of age. Age = _____.	___ ___
Histologic or cytologic confirmation of nonsquamous NSCLC. Patient should have stage IV or stage IIIB disease (AJCC TNM sixth edition; symptomatic pleural effusions should be drained prior to registration). • Although patients with squamous cell carcinomas are not eligible, adenosquamous histology is allowed.	___ ___
ECOG performance status (PS) 0, 1. PS = _____.	___ ___
Clinically significant effusions must be drained prior to treatment (e.g., symptomatic pleural effusion or ascites; if effusion produces clinically significant measurable objective changes such as hypoxia or estimated volume >500 ml effusion should be drained even if patient is asymptomatic).	___ ___
Measurable disease as defined in Section 11.0 with at least one lesion whose longest diameter can be accurately measured as ≥2.0 cm with conventional techniques or as ≥1.0 cm with spiral CT. If spiral CT is used, it must be used for both pre- and post-treatment tumor assessments.	___ ___
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	___ ___
• ANC ≥1500 μL. ANC = _____.	___ ___
• PLT ≥100,000 μL. PLT = _____.	___ ___
• Hgb ≥9 g/dL. Hgb = _____.	___ ___
• Total bilirubin ≤1.5 x upper limit of normal (ULN) or direct bilirubin ≤ULN <b>Which was done?</b> ___ Total bilirubin → Total bilirubin = _____; ULN = _____. ___ Direct bilirubin → Direct bilirubin = _____; ULN = _____. ___ Both total and direct bilirubin ( <i>enter values in above spaces.</i> )	___ ___
• AST and ALT ≤3 x ULN or AST and ALT ≤5 x ULN is acceptable if liver has tumor involvement. <b>Is there liver tumor involvement?</b> (This question may be answered yes or no). ___ Yes → AST (≤5 x ULN) = _____; ULN = _____. ALT (≤5 x ULN) = _____; ULN = _____. ___ No → AST (≤3 x ULN) = _____; ULN = _____. ALT (≤3 x ULN) = _____; ULN = _____.	___ ___
• Creatinine clearance must be ≥45 ml/min. Creatinine clearance is either measured with 24-hour urine collection or calculated using the Cockcroft-Gault formula (see Sect. 3.16). Creatinine clearance = _____.	___ ___
Prior radiation therapy is permitted as long as: • >2 weeks since last fraction of radiation administered and patient has recovered from the toxic effects of radiation treatment before study entry, except for alopecia. • ≤25% of bone marrow radiated. • Presence of measurable disease whether in-field disease progression/recurrence or disease outside the treatment fields of radiation port. • For patients receiving radiation for brain metastases, see Section 3.22.	___ ___
Ability to interrupt NSAIDs 2 days before (5 days for long-acting NSAIDs) the day of, and 2 days following administration of protocol treatment.	___ ___
Willingness to provide the biologic specimens as required by the protocol (see Sections 6.2, 14.0, 17.0).	___ ___
Able to take folic acid, vitamin B <sub>12</sub> supplementation, or dexamethasone.	___ ___
Willingness to return to NCCTG enrolling institution for follow-up.	___ ___
Ability to provide informed consent.	___ ___
Life expectancy ≥12 weeks.	___ ___
Ability to complete questionnaire(s) by themselves or with assistance.	___ ___
Willingness to enroll in N0392. Note: Participation in N0392 is mandatory for this study.	___ ___

**All responses in above section must be "Yes."**

Patient study ID number \_\_\_\_\_

**Exclusion Criteria**

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"> <li>Men or women of childbearing potential who are unwilling to employ adequate contraception</li> </ul>	___	___	
Symptomatic, untreated, or uncontrolled CNS metastases or seizure disorder. Patients with CNS metastases treated with whole brain radiation (WBRT) may be enrolled after completion of WBRT. Patients may begin chemotherapy as early as 2 weeks after WBRT. Patients treated with gamma-knife radiosurgery only for brain metastases (without WBRT) may begin chemotherapy as early as 3 days after the procedure.	___	___	
Prior chemotherapy for advanced lung cancer (except neoadjuvant or adjuvant therapy for lung cancer >12 months prior to registration).	___	___	
Symptomatic pleural and/or peritoneal effusion ( $\geq$ CTCAE v3.0 grade 2 dyspnea) that is not amenable to drainage prior to registration.	___	___	
Any clinically significant infection.	___	___	
Second primary malignancy <5 years at the time of registration with the following exceptions who are eligible regardless of date of diagnosis: <ul style="list-style-type: none"> <li>Carcinoma in situ of the cervix.</li> <li>Non-melanomatous skin cancer. History of melanoma allowed only if it was diagnosed and definitively treated at least 5 years previously with no subsequent evidence of recurrence.</li> <li>History of low-grade (Gleason score <math>\leq</math>6) localized prostate cancer (no nodal involvement).</li> <li>Treated stage I breast cancer,</li> </ul>	___	___	
History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess $\leq$ 12 months prior to registration.	___	___	
History of diverticulitis $\leq$ 12 months prior to registration.	___	___	
Any of the following prior therapies:			
<ul style="list-style-type: none"> <li>Systemic chemotherapy <math>\leq</math>12 months prior to registration. If no prior chemotherapy (<i>check NA</i>); If prior chemotherapy - Last day of chemotherapy ___/___/_____</li> </ul>	___	___	___
<ul style="list-style-type: none"> <li>Immunotherapy <math>\leq</math>12 months prior to registration. If no prior immunotherapy (<i>check NA</i>); If prior immunotherapy - Last day of immunotherapy ___/___/_____</li> </ul>	___	___	___
<ul style="list-style-type: none"> <li>Biologic therapy <math>\leq</math>12 months prior to registration. If no prior biologic therapy (<i>check NA</i>); If prior biologic therapy - Last day of biologic therapy ___/___/_____</li> </ul>	___	___	___
<ul style="list-style-type: none"> <li>Radiation therapy <math>\leq</math>2 weeks prior to registration. The site of previous radiotherapy should have evidence of progressive disease if this is the only site of disease. If no prior radiation therapy (<i>check NA</i>); If prior radiation therapy - Last day of radiation therapy ___/___/_____</li> </ul>	___	___	___
<ul style="list-style-type: none"> <li>Radiation to <math>\geq</math>25% of bone marrow</li> </ul>	___	___	
<ul style="list-style-type: none"> <li>Major surgery (i.e., laparotomy), open biopsy, or significant traumatic injury <math>\leq</math>8 weeks prior to registration. Minor surgery <math>\leq</math>4 weeks prior to registration. Insertion of a vascular access device is not considered major or minor surgery in this regard (patient is thus eligible).</li> </ul>	___	___	
<ul style="list-style-type: none"> <li>Administration of live or attenuated viral vaccine &lt;4 weeks prior to registration. If no prior viral vaccine (<i>check NA</i>); If prior viral vaccine – Last day of viral vaccine ___/___/_____</li> </ul>	___	___	___

Patient study ID number \_\_\_\_\_

**Exclusion Criteria – (continued)**

	Yes	No	NA
Any of the following concurrent severe and/or uncontrolled medical conditions: <ul style="list-style-type: none"> <li>• Hypertension, labile hypertension, or history of poor compliance with antihypertensive medication</li> <li>• Angina pectoris</li> <li>• History of congestive heart failure ≤3 months, unless ejection fraction &gt;40%</li> <li>• Myocardial infarction ≤6 months prior to registration</li> <li>• Cardiac arrhythmia</li> <li>• Diabetes mellitus</li> <li>• Interstitial pneumonia or extensive and symptomatic interstitial fibrosis of the lung</li> <li>• Active or recent history of hemoptysis &gt;1/2 teaspoon per event.</li> <li>• Ongoing or active infection</li> <li>• Psychiatric illness/social situations that would limit compliance with study requirements.</li> </ul>	_____	_____	
Serious, nonhealing wounds, ulcers, or bone fractures.	_____	_____	
Patient who is at greater than normal risk of bleeding or on any anticoagulant except those receiving low-dose warfarin or heparin for deep venous thrombosis prophylaxis (not treatment).	_____	_____	
Prior systemic therapy for stage IIIB or stage IV disease. Note: History of chemoradiation, neoadjuvant or adjuvant chemotherapy allowed if last administered dose was >12 months prior to registration.	_____	_____	
History of stroke ≤6 months prior to registration.	_____	_____	
Unwilling to, or unable to, comply with the protocol.	_____	_____	

**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
A mandatory translational research component is available for your patient; the patient will be automatically registered onto this component (Sections 3.19a, 14.0, and 17.0).	_____	_____	
Consent form signed and dated. Date informed consent signed ___/___/_____.	_____	_____	
Authorization for use and disclosure of protected health information ( <i>U.S.A. institutions only</i> ) signed and dated. If not a USA institution ( <i>check NA</i> ); If a USA institution - 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 ≤14 days after registration.	_____	_____	
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 <b>and</b> the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	_____	_____	
<b><u>Exceptions to the above dates:</u></b> <ul style="list-style-type: none"> <li>• Tumor assessment (such as chest x-ray, CT scans, PET-CT scans, MRI) must be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test date ___/___/_____; latest exception test date ___/___/_____</li> </ul>	_____	_____	
All required baseline symptoms (see Section 10.3) must be documented and graded.	_____	_____	
Study drug availability checked.	_____	_____	
Blood draw kit availability checked.	_____	_____	
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	_____	_____	
Patient has agreed to be enrolled on N0392. Note: Participation in N0392 is mandatory for this study.	_____	_____	

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

Patient study ID number \_\_\_\_\_

Registration Check (continued)

Yes No

At the time of registration/randomization, the following will also be recorded:	
• Patient has given permission to store and use blood samples for future research to learn about, prevent, or treat cancer.	___ ___
• Patient has given permission to store and use blood samples for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___ ___
• Patient has given permission to store and use tissue samples for future research to learn about, prevent, or treat cancer.	___ ___
• Patient has given permission to store and use tissue samples for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___ ___
• Patient has given permission to give their samples to outside researchers.	___ ___

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

Assigned Treatment

\_\_\_ A) ALIMTA + CBDCA + AVASTN

Person registering Signature \_\_\_\_\_ Registration Office specialist initials \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_/\_\_/\_\_\_\_