

Eligibility Checklist

11/06/2009

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N0626: Phase II Randomized Study of Pemetrexed With Sorafenib Versus Pemetrexed Alone as Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer

**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) __/__/_____
<b>Person Completing Form:</b>
Last Name: <b>(print)</b> _____ First Name: <b>(print)</b> _____
Phone: _____ Fax: _____ Email: _____

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

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

≥18 years of age. Age = _____.	___ ___
Histologic or cytologic confirmation of non-squamous 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.	___ ___
Patients must have 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.	___ ___
Prior radiation therapy is permitted as long as: • 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.	___ ___
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. Which was done? ___ Total bilirubin → Total bilirubin = _____; ULN = _____. ___ Direct bilirubin → Direct bilirubin = _____; ULN = _____. ___ Both total and direct bilirubin → Complete both total and direct bilirubin above.	___ ___
• AST and ALT ≤3 x ULN or AST and ALT ≤5 x ULN is acceptable if liver has tumor involvement. <b>Does liver have tumor involvement?</b> (This question may be answered yes or no.) ___ Yes (≤5 x ULN) → AST = _____; ULN = _____. ALT = _____; ULN = _____. ___ No (≤3 x ULN) → AST = _____; ULN = _____. ALT = _____; ULN = _____.	___ ___
• INR <1.5 or a PT/PTT within normal limits (WNL). Patients receiving anticoagulation treatment with an agent such as warfarin or <b>prophylactic dose</b> heparin <b>are</b> eligible if the parameters as outlined are met at the individual patient's stable dose of the anticoagulants. Which was done and within normal limits? ___ INR → INR (<1.5) = _____ ___ PT or PTT → PT or PTT (WNL) = _____; LLN = _____; ULN = _____.	___ ___
• Calculated creatinine clearance must be ≥45 ml/min using the Cockcroft-Gault formula (see Section 3.15). Creatinine clearance = _____.	___ ___
ECOG performance status (PS) 0 and 1.	___ ___
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (check NA) vs. Negative pregnancy test date ___/___/___	___ ___ ___
Ability to provide informed consent.	___ ___
Life expectancy ≥12 weeks.	___ ___
Willingness to provide the biologic specimens as required by the protocol (see Sections 6.13, 14.0, 17.0). (Please note that the willingness to participate pertains only to the patient and does not factor in the institution's ability to participate in any part of the translational component.)	___ ___

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

Eligibility Check – (Required Characteristics continued)

Yes No

NA

Willingness to return to NCCTG enrolling institution for follow-up.	___ ___
Previously treated with 1 chemotherapy regimen. Prior treatment with adjuvant chemotherapy is allowed and not counted as a regimen.	___ ___
Able to take folic acid, vitamin B <sub>12</sub> supplementation, and dexamethasone.	___ ___
Able to permanently discontinue aspirin dose of $\geq 1.3$ grams/day $\geq 10$ days before and after pemetrexed treatment.	___ ___
Stable brain metastasis that have been treated with either whole brain radiation therapy or gamma knife surgery and are off steroid treatment for $>4$ weeks.	___ ___

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

**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"> <li>• Pregnant women</li> <li>• Nursing women</li> <li>• Men or women of childbearing potential who are unwilling to employ adequate contraception.</li> </ul>	___ ___
Any clinically significant infection.	___ ___
Known HIV-positive patients. Those receiving anti-retroviral therapy are also excluded because of possible pharmacokinetic interactions with sorafenib and the possible unfavorable immunosuppressive effects of sorafenib.	___ ___
Evidence or history of bleeding diathesis or coagulopathy.	___ ___
Serious non-healing wound, ulcer, or bone fracture.	___ ___
Any of the following prior therapies:	
• Prior radiation to $>25\%$ of bone marrow.	___ ___
• Sorafenib.	___ ___
• Pemetrexed	___ ___
• Chemotherapy $\leq 3$ weeks prior to registration. No prior chemotherapy ( <i>check NA</i> ) vs. Last day of chemotherapy ___ / ___ / ___.	___ ___
• Mitomycin C/nitrosoureas $\leq 6$ weeks prior to registration. No prior Mitomycin C/nitrosoureas therapy ( <i>check NA</i> ) vs Last day of mitomycin C/nitrosoureas therapy ___ / ___ / ___.	___ ___
• Immunotherapy $\leq 2$ weeks prior to registration. No prior immunotherapy ( <i>check NA</i> ) vs. Last day of immunotherapy ___ / ___ / ___.	___ ___
• Biologic therapy $\leq 2$ weeks prior to registration. No prior biologic therapy ( <i>check NA</i> ) vs. Last day of biologic therapy ___ / ___ / ___.	___ ___
• Gene therapy $\leq 2$ weeks prior to registration. No prior gene therapy ( <i>check NA</i> ) vs. Last day of gene therapy ___ / ___ / ___.	___ ___
• Full field radiation therapy $\leq 4$ weeks prior to registration. No prior full field radiation therapy ( <i>check NA</i> ) vs. Last day of full field radiation therapy ___ / ___ / ___.	___ ___
• Limited field radiation therapy $\leq 2$ weeks prior to registration. No prior limited field radiation therapy ( <i>check NA</i> ) vs. Last day of limited field radiation therapy ___ / ___ / ___.	___ ___

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

Eligibility Check – (Contraindications continued)

Yes No NA

<ul style="list-style-type: none"> <li>Major surgery (i.e., laparotomy), open biopsy, or significant traumatic injury <math>\leq 4</math> weeks prior to registration or anticipation of need for major surgical procedure during the course of the study. Minor surgery <math>\leq 2</math> weeks prior to registration. Insertion of a vascular access device is not considered major or minor surgery in this regard.</li> </ul>	<p>___ ___</p>
Other chemotherapy, immunotherapy, hormonal therapy, radiotherapy, or any ancillary therapy considered investigational (utilized for a non-FDA-approved indication and in the context of a research investigation) $\leq 4$ weeks prior to registration.	<p>___ ___</p>
Patients with brain metastasis that require steroid therapy.	<p>___ ___</p>
Any bleeding $\geq$ grade 2 $\leq 4$ weeks prior to registration (EXCEPTION: Grade 2 petechiae).	<p>___ ___</p>
Second primary malignancy except carcinoma in situ of the cervix or non-melanomatous skin cancer, unless that prior malignancy was diagnosed and definitively treated $\geq 5$ years previously with no subsequent evidence of recurrence. Patients with a history of low-grade (Gleason score $\leq 6$ ) localized prostate cancer will be eligible even if diagnosed $< 5$ years prior to registration. Patients with a history of DCIS that has been definitively treated will be eligible even if diagnosed $< 5$ years prior to registration.	<p>___ ___</p>
Patients with only non-measurable disease, including small lesions whose longest diameter measures $< 2$ cm with conventional techniques or $< 1.0$ cm with spiral CT, and truly non-measurable lesions, which include the following: <ul style="list-style-type: none"> <li>Bone lesions.</li> <li>Leptomeningeal disease.</li> <li>Ascites.</li> <li>Pleural/pericardial effusion.</li> <li>Inflammatory breast disease.</li> <li>Lymphangitis cutis/pulmonis.</li> <li>Abdominal masses that are not confirmed and followed by imaging techniques.</li> <li>Cystic lesions.</li> </ul>	<p>___ ___</p>
Any other severe underlying diseases which are, in the judgment of the investigator, inappropriate for entry into this study including uncontrolled hypertension.	<p>___ ___</p>
Inability to swallow pills.	<p>___ ___</p>
Any of the following concurrent severe and/or uncontrolled medical conditions: <ul style="list-style-type: none"> <li>Uncontrolled blood pressure defined as systolic <math>&gt; 150</math> mmHg and/or diastolic <math>&gt; 100</math> mmHg, in spite of adequate anti-hypertensive therapy.</li> <li>Angina pectoris.</li> <li>History of congestive heart failure <math>\leq 3</math> months, unless ejection fraction <math>&gt; 40\%</math>.</li> <li>Myocardial infarction <math>\leq 6</math> months prior to registration.</li> <li>Cardiac arrhythmia.</li> <li>Diabetes mellitus.</li> <li>Active hemoptysis.</li> </ul>	<p>___ ___</p>
Receiving therapeutic anticoagulation. Prophylactic anticoagulation (i.e. low dose warfarin) of venous or arterial access devices is allowed provided that the requirements for PT, INR, or PTT are met.	<p>___ ___</p>
Serious condition that, in the opinion of the investigator, would compromise the patient’s ability to complete the study or increase the risk for serious adverse events.	<p>___ ___</p>
Symptomatic serosal effusion ( $\geq$ CTCAE v3.0 grade 2 dyspnea) that is not amenable to drainage prior to registration.	<p>___ ___</p>
Use of St. John’s Wort that cannot be completely stopped for the duration of the study (because of the effects on hepatic drug metabolism).	<p>___ ___</p>
Prior therapy with agents that target VEGF, VEGF receptor or VEGF receptor tyrosine kinase inhibitors. Exception: Prior therapy with bevacizumab is allowed.	<p>___ ___</p>

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

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

**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.(U.S.A. institutions only) Not a USA institution (check NA) vs. Date of authorization ____/____/____.	___	___	___
A mandatory translational research component is available for your patient, the subject will be automatically registered onto this component (Section 3.19b, 14.0, and 17.0).	___	___	___
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>Exceptions to the above dates:</b> Tumor assessment and chest x-ray (if not used for tumor assessment) performed ≤28 days prior to registration (see Section 4.0). Earliest exception test/procedure date ____/____/____; Latest exception test/procedure date ____/____/____.	___	___	___
All required baseline symptoms must be documented and graded.	___	___	___
Study drug availability checked.	___	___	___
Treatment assignment will be calculated using a dynamic allocation procedure which balances the marginal distributions of the stratification factors between the treatment groups. The factors defined in Section 5.0 will be used as stratification factors.	___	___	___

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

*At the time of registration/randomization the following will also be recorded:*

	Yes	No
• Patient has given permission for tissue sample(s) to be stored and used for future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission for tissue sample(s) to be stored and used 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 for blood sample(s) to be stored and used for future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission for blood sample(s) to be stored and used for 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 contact them in the future to ask them to take part in more research.	___	___
Patient has agreed to take part in N0392.	___	___

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

**Stratification Factors:**

ECOG PS (check one):

\_\_\_ 0  
\_\_\_ 1

**Assigned Treatment**

\_\_\_ A) ALIMTA + BAY439006  
\_\_\_ B) ALIMTA

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

Physician \_\_\_\_\_ Signature  
M D Y