

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

09/11/2009

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N0775: A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma

**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) _____	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 May 15, 2009, IRB approved?

\_\_\_ Yes. If Yes, Addendum 2 approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

\_\_\_ No. If No, End form, Addendum 2 approval required.

Addendum 5 dated August 14, 2009, IRB approved?

\_\_\_ Yes. If Yes, Addendum 5 approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

\_\_\_ No. If No, End form, Addendum 5 approval required.

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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

Histologic proof of stage IV malignant melanoma not amenable to surgery. Note: Prior adjuvant chemotherapy and/or immunotherapy is allowed.	___	___	___
Measurable disease with at least one lesion whose longest diameter can be measured as $\geq 20$ mm by CT or MRI scans or $\geq 10$ mm by spiral CT. Note: Disease that is measurable by physical examination only is not eligible.	___	___	___
Life expectancy of $\geq 4$ months.	___	___	___
$\geq 18$ years of age. Age = _____.	___	___	___
ECOG performance score (PS) of 0 or 1.	___	___	___
The following laboratory values obtained $\leq 14$ days prior to registration/randomization. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	___	___	___
• ANC $\geq 1500$ /mL. ANC = _____.	___	___	___
• PLT $\geq 100,000$ . PLT = _____.	___	___	___
• Hgb $\geq 9$ g/dL (patients may be transfused to meet this requirement.) Hgb = _____.	___	___	___
• Creatinine $\leq 1.5$ x institutional upper limit of normal (ULN). Creatinine = _____; ULN = _____.	___	___	___
• Total bili $\leq 1.5$ mg/dL (exception: Patients with documented Gilbert's syndrome are allowed to participate despite elevated bilirubin.) <b>Does patient have documented Gilbert's syndrome?</b> (This question may be answered yes or no.) ___ Yes, patient with Gilbert's syndrome $\rightarrow$ Bili = _____. ___ No, not a patient with Gilbert's syndrome $\rightarrow$ Bili ( $\leq 1.5$ ) = _____.	___	___	___
• AST $\leq 2.5$ x ULN. AST = _____; ULN = _____.	___	___	___
• Alk phos $\leq 2.5$ x ULN. Alk phos = _____; ULN = _____.	___	___	___
• Proteinuria at screening as demonstrated by one of the following: o Urine protein:creatinine (UPC) ratio $< 1.0$ at screening OR o Urine dipstick for proteinuria $< 2+$ (patients discovered to have $\geq 2+$ proteinuria on dipstick urinalysis at baseline should undergo a 24-hour urine collection and must demonstrate $\leq 1$ g of protein in 24 hours to be eligible).	___	___	___
Negative serum pregnancy test done $\leq 7$ days prior to registration/randomization, for women of childbearing potential only. Not a woman of childbearing potential ( <i>check NA</i> ) vs. negative pregnancy test date ___/___/_____	___	___	___
Ability to understand and the willingness to sign a written informed consent document.	___	___	___
Willingness to return to an NCCTG institution for follow-up.	___	___	___
Patient willing to provide mandatory blood samples for research purposes (see Sections 6.13 and 14.0).	___	___	___

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

**Exclusion Criteria**

Yes No NA

Prior treatment with agents disrupting VEGF activity (i.e. Avastin®, VEGF-trap, anti-VEGFR Mab.)	___	___	___
Brain metastases per MRI or CT.	___	___	___
Other investigational agents $\leq 4$ weeks prior to registration/randomization.	___	___	___
Major surgical procedure, open biopsy, or significant traumatic injury $\leq 4$ weeks prior to registration/randomization. • Fine needle aspirations or core biopsies $\leq 7$ days prior to registration/randomization. • Planned/or anticipated major surgical procedure during the course of the study.	___	___	___

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

Exclusion Criteria—*continued*

Yes No

Other medical conditions including but not limited to: <ul style="list-style-type: none"> <li>• Active infection requiring parenteral antibiotics</li> <li>• Poorly controlled high blood pressure (<math>\geq 150</math> mm Hg systolic and/or 100 mmHg diastolic) despite treatment.</li> <li>• New York Heart Association class II-IV congestive heart failure.</li> <li>• Serious cardiac arrhythmia requiring medication.</li> <li>• Myocardial infarction or unstable angina <math>\leq 6</math> months prior to registration/randomization.</li> <li>• Clinically significant peripheral vascular disease.</li> <li>• Deep venous thrombosis or pulmonary embolus <math>\leq 1</math> year of registration/randomization and/or ongoing need for full-dose oral or parenteral anticoagulation.</li> <li>• Ongoing anti-platelet treatment other than low-dose aspirin (i.e., aspirin 81 mg p.o. daily).</li> <li>• Active bleeding or pathological conditions that carry high risk of bleeding (e.g., known esophageal varices, etc.).</li> <li>• Serious, non-healing wound (including wounds healing by secondary intention), ulcer or bone fracture.</li> <li>• History of abdominal fistula, gastrointestinal perforation or intra-abdominal abscess <math>\leq 6</math> months prior to registration/randomization.</li> <li>• History of CNS disease (e.g., primary brain tumor, vascular abnormalities, etc.), clinically significant stroke or TIA <math>\leq 6</math> months prior to registration/randomization, seizures not controlled with standard medical therapy.</li> <li>• Radiographically documented invasion of adjacent organs (duodenum, stomach, etc.) or tumor invading major blood vessels.</li> <li>• History of hypertensive crisis or hypertensive encephalopathy.</li> </ul>	_____	_____
Any of the following as this regimen may be harmful to a developing fetus or nursing child: <ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Nursing women</li> <li>• Women of childbearing potential or their sexual partners who are unwilling to employ adequate contraception</li> </ul>	_____	_____
Existence of peripheral neuropathy $\geq$ grade 2.	_____	_____
History of other malignancy $\leq 5$ years with the exception of basal cell or squamous cell carcinoma of the skin, treated with local resection only, or carcinoma in situ of the cervix.	_____	_____
Prior chemotherapy in the metastatic setting.	_____	_____
Prior treatment with sunitinib malate or sorafenib.	_____	_____
Prior treatment with any taxane-based chemotherapy.	_____	_____
$\leq 4$ weeks since last day of adjuvant radiation therapy prior to registration or $\leq 2$ weeks since last day of palliative radiation therapy. NOTE: Patients who have had $>25\%$ of their functional bone marrow irradiated are not eligible for this trial. Last day of <u>adjuvant</u> radiation therapy ____/____/_____. (Leave blank if no prior <u>adjuvant</u> radiation therapy.) Last day of <u>palliative</u> radiation therapy ____/____/_____. (Leave blank if no prior <u>palliative</u> radiation therapy.)	_____	_____
Active or recent history of hemoptysis ( $\geq 1/2$ teaspoon of bright red blood per episode) $\leq 30$ days prior to registration.	_____	_____
Known hypersensitivity to any of the components of Avastin®.	_____	_____
Known to be HIV positive.	_____	_____
Current or known history of hepatitis.	_____	_____

**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. <b>Non-USA institution only</b> (check NA) vs. Date of authorization ____/____/____.	_____	_____	_____
A mandatory translational research component is part of this study, the patient will be automatically registered onto this component (Section 14.0).	_____	_____	_____

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Registration Check – (continued)

Yes No

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 ≤7 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>Exception to the above dates:</u></b> • Brain MRI (or CT if MRI cannot be performed) must be completed ≤28 days prior to registration. Brain MRI (or CT) date ___/___/____		
All required baseline symptoms must be documented and graded.	___	___
Study drug availability checked.	___	___
Kit availability checked.	___	___

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

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

▪ Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat cancer.	___	___
▪ Patient has given permission to store and use blood sample(s) for future research to learn, prevent, or treat other health problems.	___	___
▪ Patient has given NCCTG permission to give blood sample(s) to outside researchers.	___	___
Patient has agreed to be enrolled on N0392.	___	___

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

Stratification Factors

ECOG Performance Status (PS) (*check one*):

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

Location of metastatic disease (*check one*):

\_\_\_ M1a (skin or subcutaneous tissue or lymph node only)  
\_\_\_ M1b (lung)  
\_\_\_ M1c (other visceral sites)

Assigned Treatment

\_\_\_ NA A) Temozolomide + Bevacizumab (*Arm A closed to accrual as of 8/21/2009*)

\_\_\_ B) Bevacizumab + ABI-007 + CBDCA

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

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