

NORTH CENTRAL CANCER TREATMENT GROUP
Registration (Step 2) Eligibility Checklist

11/13/2009
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N0776: **Phase II Trial of Avastin® in Combination with Sorafenib in Recurrent Glioblastoma Multiforme**

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) _____
(For Mayo Rochester patients, include first four letters of last name.)

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

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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

≥18 years of age. Age = _____	____	____	____
Histological confirmation of glioblastoma multiforme as determined by pre-registration central pathology review. NOTE: Gliosarcomas are eligible	____	____	____
Evidence of tumor progression by MRI or CT scan following RT or following the most recent anti-tumor therapy.	____	____	____
Bidimensionally measurable or evaluable disease by MRI or CT scan.	____	____	____
ECOG Performance Status (PS) 0, 1, or 2. PS = _____	____	____	____
≤1 chemotherapy regimen for progressive/recurrent disease.	____	____	____
≥12 weeks since the completion of RT.	____	____	____
The following laboratory values obtained ≤21 days prior to registration. Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
• ANC ≥1500 ANC = _____	____	____	____
• PLT ≥100,000 PLT = _____	____	____	____
• Hgb >9.0 g/dL HgB = _____	____	____	____
• T. bili ≤1.5 x UNL T. bili = _____; UNL = _____	____	____	____
• SGOT (AST) ≤3 x UNL SGOT (AST) = _____; UNL = _____	____	____	____
• Creatinine ≤ UNL Creatinine = _____; UNL = _____	____	____	____
UPC ratio <1. NOTE: Urine protein must be screened by urine analysis for Urine Protein Creatinine (UPC) ratio. For UPC ratio ≥1.0, 24-hour urine protein must be obtained and the level should be <1000 mg.	____	____	____
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 ____/____/____	____	____	____
Ability to complete questionnaire(s) by themselves or with assistance.	____	____	____
Provide informed written consent.	____	____	____
Willingness to return to NCCTG enrolling institution for follow-up.	____	____	____
Patient willing to provide mandatory blood samples for research purposes (see Sections 6.22 and 14.0).	____	____	____
Fixed dose of corticosteroids (or no corticosteroids) ≥1 week prior to baseline scan.	____	____	____

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

Exclusion Criteria

Yes No NA

Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception during the study and up to 6 months after the last treatment dose <p>Note: Avastin® and sorafenib are investigational agents whose genotoxic effects on the developing fetus and newborn are unknown.</p>	____	____	____
Prior intratumoral chemotherapy, stereotactic radiosurgery or interstitial brachytherapy. EXCEPTION: Separate lesion on MRI which is not part of the previous treatment field or there is proof of recurrent disease based on biopsy, MRI spectroscopy, or PET scan.	____	____	____
Inadequately controlled hypertension (systolic blood pressure of >150 mmHg or diastolic pressure >100 mmHg on anti-hypertensive medications). NOTE: Patients with well-controlled hypertension are eligible.	____	____	____
Receiving enzyme-inducing antiepileptic drugs (EIAcS; e.g., phenytoin, fosphenytoin, carbamazepine, phenobarbital, or primidone) or any other potent CYP3A4 inducer such as rifampin or St. John’s wort. Note: See Appendix IV for a complete list.	____	____	____

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Exclusion Criteria – (continued)

Yes No NA

	Yes	No	NA
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.	___	___	___
Immunocompromised patients (other than that related to the use of corticosteroids) including patients known to be HIV positive.	___	___	___
Any condition (e.g., gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, or prior surgical procedures affecting absorption) that impairs ability to swallow pills.	___	___	___
Receiving therapeutic anticoagulation with Coumadin. NOTE: Prophylactic anticoagulation (i.e., low dose warfarin) of venous or arterial access devices is allowed, provided that INR <1.5. Therapeutic anti-coagulation with low molecular weight heparin is allowed at time of registration and during the study if needed.	___	___	___
Evidence of bleeding diathesis (greater than normal risk of bleeding) or coagulopathy (in the absence of therapeutic anticoagulation).	___	___	___
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.	___	___	___
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.	___	___	___
Other active malignancy ≤3 years prior to registration. EXCEPTIONS: Non-melanotic skin cancer or carcinoma-in-situ of the cervix. NOTE: If there is a history of prior malignancy, they must not be receiving other specific treatment (other than hormonal therapy) for their cancer.	___	___	___
History of myocardial infarction or unstable angina ≤6 months prior to registration, or congestive heart failure requiring use of ongoing maintenance therapy for life-threatening ventricular arrhythmias.	___	___	___
New York Heart Association (NYHA) ≥Class II CHF.	___	___	___
Core biopsy or other minor surgical procedures ≤7 days prior to registration. NOTE: Placement of a vascular access device is allowed.	___	___	___
Major surgical procedure, open biopsy, or significant traumatic injury ≤28 days prior to registration or anticipation of need for major surgical procedure during the course of the study.	___	___	___
Significant vascular disease (e.g., aortic aneurysm, aortic dissection) or recent peripheral arterial thrombosis ≤6 months prior to registration.	___	___	___
History of hypertensive crisis or hypertensive encephalopathy.	___	___	___
Known hypersensitivity to any of the components of sorafenib or Avastin®.	___	___	___
Serious, nonhealing wounds, ulcers, or bone fractures.	___	___	___
History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess ≤6 months prior to registration.	___	___	___
Active or recent history of hemoptysis (≥1/2 teaspoon of bright red blood per episode) ≤30 days prior to registration.	___	___	___
Prior anti-angiogenic therapy.	___	___	___
History of stroke or transient ischemic attack (TIA) ≤6 months prior to registration.	___	___	___
Any evidence of CNS hemorrhage on baseline CT or MRI. Note: T1 hyperintensity confined to the surgical cavity, which is felt likely due to post surgical blood contaminating the intracavity CSF or irrigation that have not yet absorbed, and which is not felt to clinically or radiographically represent new spontaneous hemorrhage, would be acceptable. Old blood products or hemosiderin, without a history of spontaneous bleeding, would also be acceptable. If there are questions or concerns, the investigator should discuss the individual situation directly with the protocol PI	___	___	___

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Exclusion Criteria – (continued)

Yes No NA

Any of the following:	Yes	No	NA
<ul style="list-style-type: none"> ≤ 6 weeks since last day of nitrosourea-based chemotherapy If no prior nitrosourea-based chemotherapy (<i>check NA</i>); If prior nitrosourea-based chemotherapy – Last day of nitrosourea-based chemotherapy ___/___/_____ 	___	___	___
and/or <ul style="list-style-type: none"> ≤ 4 weeks since last day of other chemotherapy prior to registration If no other chemotherapy (<i>check NA</i>) If other chemotherapy – Last day of other chemotherapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> ≤ 2 weeks since last day of small cell cycle inhibitors prior to registration If no prior small cell cycle inhibitors (<i>check NA</i>); If prior small cell cycle inhibitors – Last day of small cell cycle inhibitors ___/___/_____ 	___	___	___

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

A mandatory translational research component for blood is part of this study; the patient will be automatically registered onto this component (Sections 3.29f and 14.0).	___	___	___
Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.	___	___	___
Treatment cannot begin prior to registration and must begin ≤14 days after registration.	___	___	___
Pretreatment tests/procedures must be completed ≤21 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.	___	___	___
Blood draw kit availability checked.	___	___	___
Patient questionnaire FACT-Br booklet availability checked; copies are not acceptable for this submission.	___	___	___

All responses in above section must be “Yes.”

An optional translational research component for tissue is part of this study. There will be an option to select if the patient is to be registered onto this component (Section 17.3). <ul style="list-style-type: none"> 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 tissue sample(s) for use in future research to learn about, prevent, or treat cancer. 	___	___	___
<ul style="list-style-type: none"> Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer. 	___	___	___
<ul style="list-style-type: none"> Patient has given permission to keep tissue 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). 	___	___	___
<ul style="list-style-type: none"> Patient has given permission to keep blood 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). 	___	___	___
<ul style="list-style-type: none"> Patient has given NCCTG permission to give tissue sample(s) to outside researchers. 	___	___	___
<ul style="list-style-type: none"> Patient has given NCCTG permission to give blood sample(s) to outside researchers. 	___	___	___
<ul style="list-style-type: none"> Patient has given NCCTG permission to be contacted in the future to take part in more research. 	___	___	___
Patient has agreed to be enrolled on N0392.	___	___	___

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

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Patient study ID number _____

Assigned Treatment

_____ A) 439006 + AVASTN

Person registering Signature _____ Registration Office specialist initials _____

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