

NORTH CENTRAL CANCER TREATMENT GROUP

Registration (Step 2) Eligibility Checklist

9/28/2011  
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N0572: A Phase I/II Trial of Sorafenib and CCI-779 in Patients with Recurrent Glioblastoma

**To register a patient, call (507/284-4130) or fax (507/284-0885) a completed (Step 2) registration eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.**

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.)	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) ___/___/_____ Zip code _____	<input type="checkbox"/> Black or African American
Country of Residence _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
	<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 M/D/Y.

Yes No

**Required Characteristics**

- \_\_\_\_ \_\_\_\_ ≤2 prior systemic chemotherapy regimens.
- \_\_\_\_ \_\_\_\_ ≥18 years of age. Age = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Histological confirmation of a grade 4 astrocytoma (glioblastoma) or gliosarcoma, at primary diagnosis or recurrence by WHO criteria (see Section 17.0). Central pathology review is mandatory prior to study entry to confirm eligibility.
- \_\_\_\_ \_\_\_\_ 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.
- \_\_\_\_ \_\_\_\_ ≥12 weeks since the completion of RT. Last day of RT \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Fixed or decreasing dose of corticosteroids (or no corticosteroids) ≥1 week prior to registration.
- \_\_\_\_ \_\_\_\_ Corticosteroids start date \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ ≥1 week from minor surgery other than venous line placement and >3 weeks from major surgery (except for patients undergoing tumor tissue acquisition as discussed in Section 7).
- \_\_\_\_ \_\_\_\_ Date of minor surgery \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Date of major surgery \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ ≥4 weeks from prior cytotoxic chemotherapy (≥6 weeks for nitrosoureas).
- \_\_\_\_ \_\_\_\_ Last day of cytotoxic chemotherapy \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ Last day of nitrosoureas \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ ≥2 weeks from cytostatic chemotherapy such as tamoxifen, cis-retinoic acid, or thalidomide (address questions regarding such agents to study chair).
- \_\_\_\_ \_\_\_\_ Last day of cytostatic chemotherapy \_\_\_\_ - \_\_\_\_ - \_\_\_\_ vs. not applicable \_\_\_\_.
- \_\_\_\_ \_\_\_\_ The following laboratory values obtained ≤7 days prior to registration. Earliest laboratory test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_; latest laboratory test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_ . NOTE: These dates pertain to the following labs only.
  - \_\_\_\_ \_\_\_\_ • WBC ≥3000/mm<sup>3</sup>. WBC = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • ANC ≥1500/mm<sup>3</sup>. ANC = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • PLT ≥100,000/mm<sup>3</sup>. PLT = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Hgb ≥10 gm/dL. Hgb = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Total bilirubin ≤1.5 x ULN. Note see section 7.2 for starting dose of temsirolimus if bilirubin is >1.0 and ≤1.5 x ULN  
Total bilirubin = \_\_\_\_\_; ULN = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • SGOT (AST) ≤2.5 x ULN. SGOT (AST) = \_\_\_\_\_; ULN = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Creatinine ≤2.0 x ULN. Creatinine = \_\_\_\_\_; ULN = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Serum cholesterol ≤350 mg/dL. Serum cholesterol = \_\_\_\_\_.
  - \_\_\_\_ \_\_\_\_ • Serum triglycerides ≤400 mg/dL. Serum triglycerides = \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ Willingness to provide the biologic specimens as required by the protocol. (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.)

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

**Contraindications**

- \_\_\_\_ \_\_\_\_ Prior intratumoral chemotherapy (e.g. Gliadel or IL13-PE38QQR), stereotactic radiosurgery or interstitial brachytherapy unless there is a 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.
- \_\_\_\_ \_\_\_\_ Prior CCI-779, sorafenib, or other agents specifically targeting mTOR or raf. Patients receiving prior agents inhibiting VEGF or VEGFR (prior anti-VEGF group) are eligible but: 1) must be at least four weeks from last treatment with the agent(s); and 2) must have recovered from any clinically relevant toxicities attributable to this agent(s).

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

**Eligibility Check – Contraindications** (*continued*)

Yes No

- |       |       |  |
|-------|-------|--|
| _____ | _____ | Evidence of bleeding diathesis or coagulopathy.  |
|       |       | <ul style="list-style-type: none"> <li>• Note: Patients on prophylactic anticoagulation therapy (e.g., low-dose warfarin) are eligible provided their coagulation parameter levels are as follows: prothrombin time (INR; International Normalized Ratio of prothrombin time) &lt;1.1 x institutional upper limit of normal.</li> <li>• Note: Patients on full-dose anticoagulants (e.g. warfarin) are eligible provided that both of the following criteria are met: a) the patient has an in-range INR (usually between 2 and 3) on a stable dose of oral anticoagulant or on a stable dose of low molecular weight heparin, and b) the patient has no active bleeding or pathological condition that carries a high risk of bleeding (e.g., tumor involving major vessels or known varices).</li> </ul> |
| _____ | _____ | INR >1.5 (unless the patient is on full dose warfarin).  |
| _____ | _____ | Receiving enzyme-inducing antiepileptic drugs (EIAEDs; 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.   |
| _____ | _____ | Any condition (e.g., gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active peptic ulcer disease) that impairs their ability to swallow pills.   |
| _____ | _____ | Hypertension with systolic blood pressure of >140 mmHg or diastolic pressure >90 mmHg. However, patients with well-controlled hypertension are eligible.   |
| _____ | _____ | Uncontrolled infection.  |
| _____ | _____ | Any of the following because CCI-779 and sorafenib are investigational agents whose genotoxic effects on the developing fetus and newborn are unknown: <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> Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.  |
| _____ | _____ | Known hypersensitivity to any of the components of CCI-779 or sorafenib.   |
| _____ | _____ | Other active malignancy.   |
| _____ | _____ | 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.  |
| _____ | _____ | Immunocompromised patients (other than that related to the use of corticosteroids) including patients known to be HIV positive. HIV-positive patients on combination antiretroviral therapy are ineligible because of the potential for pharmacokinetic interactions with CCI-779 and sorafenib.   |
| _____ | _____ | Receiving any investigational agents other than CCI-779 or sorafenib.  |
| _____ | _____ | Significant intratumoral, intracerebral, or subarachnoid hemorrhage on baseline MRI or CT, or other history of significant intratumoral, intracerebral, or subarachnoid hemorrhage.  |

**All responses in above section must be “No.”**

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

**Registration Check** - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- \_\_\_\_ \_\_\_\_ A mandatory translational research component is part of this study; the patient will be automatically registered on this component (Section 3.29e and 14.111).
- \_\_\_\_ \_\_\_\_ 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  $\leq 14$  days after registration.
- \_\_\_\_ \_\_\_\_ Pretreatment tests/procedures must be completed  $\leq 21$  days prior to registration (see Section 4.0). Earliest pretreatment test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_; latest pretreatment test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_\_. NOTE: The earliest pretreatment test date(s) 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(s).
- \_\_\_\_ \_\_\_\_ ***Exceptions to the above dates:***
  - Hematology, chemistry, and serum pregnancy test, for women of childbearing potential only,  $\leq 7$  days prior to registration (see Section 4.0). Earliest exception test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_; latest exception test date \_\_\_\_ - \_\_\_\_ - \_\_\_\_.
  - If serum pregnancy test not done, reason: \_\_\_\_\_.
- \_\_\_\_ \_\_\_\_ All required baseline symptoms must be documented and graded.
- \_\_\_\_ \_\_\_\_ Study drug availability checked.
- \_\_\_\_ \_\_\_\_ Blood draw kit availability checked.

**All responses in above section must be “Yes.”**

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

- \_\_\_\_ \_\_\_\_ • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer.
- \_\_\_\_ \_\_\_\_ • Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer.
- \_\_\_\_ \_\_\_\_ • 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).
- \_\_\_\_ \_\_\_\_ • 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).
- \_\_\_\_ \_\_\_\_ • Patient has given permission for his/her tissue sample to be used for genetic research.
- \_\_\_\_ \_\_\_\_ • Patient has given permission for his/her blood sample to be used for genetic research.
- \_\_\_\_ \_\_\_\_ • Patient has given NCCTG permission to give his/her tissue sample(s) to outside researchers.
- \_\_\_\_ \_\_\_\_ • Patient has given NCCTG permission to give his/her blood sample(s) to outside researchers.
- \_\_\_\_ \_\_\_\_ • Patient has given permission to be contacted in the future to take part in more research.

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

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

Grouping Factors

Phase I

NA Non-surgical patients only (PHASE I CLOSED TO ACCRUAL AS OF ADDENDUM 5)

Phase II (PHASE II OPENED TO ACCRUAL AS OF ADDENDUM 5)

NA Group 1: Patients not undergoing biopsy/surgery following study drug exposure

[Study 2, Group 1 (Arm B) only (CLOSED TO ACCRUAL AS OF 9/27/2011)]

\_\_\_\_\_ Group 2: Patients undergoing biopsy/surgery following study drug exposure

\_\_\_\_\_ Group 3: Patients with prior anti-VEGF treatments

Descriptive Factors

Age (years)

\_\_\_\_\_ ≤40

\_\_\_\_\_ 41-60

\_\_\_\_\_ >60

Non-enzyme inducing

anticonvulsant use at study entry

\_\_\_\_\_ Yes

\_\_\_\_\_ No

ECOG PS

\_\_\_\_\_ 0

\_\_\_\_\_ 1

\_\_\_\_\_ 2

Prior temozolomide

\_\_\_\_\_ Yes

\_\_\_\_\_ No

Prior nitrosoureas

\_\_\_\_\_ Yes

\_\_\_\_\_ No

Interval since end of RT

(months): \_\_\_\_\_

Corticosteroid therapy

at study entry

\_\_\_\_\_ Yes

\_\_\_\_\_ No

Extent of primary resection

\_\_\_\_\_ None

\_\_\_\_\_ Biopsy

\_\_\_\_\_ Subtotal resection

\_\_\_\_\_ Gross total resection

Extent of resection at

recurrence

\_\_\_\_\_ None

\_\_\_\_\_ Biopsy

\_\_\_\_\_ Subtotal resection

\_\_\_\_\_ Gross total resection

Family history of brain tumor

\_\_\_\_\_ Yes → If yes, check all that apply

\_\_\_\_\_ Father

\_\_\_\_\_ Mother

\_\_\_\_\_ Brother/Sister

\_\_\_\_\_ Child

\_\_\_\_\_ Other (list: \_\_\_\_\_)

\_\_\_\_\_ No

Primary indicator

\_\_\_\_\_ Measurable

\_\_\_\_\_ Evaluable

Prior treatment with anti-VEGF/VEGR or  
VEGF kinase agents

\_\_\_\_\_ Yes

\_\_\_\_\_ No

Baseline total bilirubin

\_\_\_\_\_ ≤1.0 x ULN

\_\_\_\_\_ >1.0 x ULN

Subgroup code (for Full CDUS reporting):

NA SG1 Phase I Patients with recurrent GBM's

NA SG2 Phase II Patients not undergoing biopsy/surgery following study drug exposure

[Study 2, Group 1 (Arm B) only (CLOSED TO ACCRUAL AS OF 9/27/2011)]

\_\_\_\_\_ SG3 Phase II Patients undergoing biopsy/surgery following study drug exposure

\_\_\_\_\_ SG4 Phase II Patients with prior anti-VEGF treatments

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

Assigned Treatment

- NA A) CCI-779\* + Sorafenib\*\* [*Phase I only (PHASE I CLOSED TO ACCRUAL AS OF ADDENDUM 5)*]  
NA B) CCI-779\* + Sorafenib\*\* (Patients NOT undergoing biopsy/surgery) [*Study 2, Group 1 (Arm B) only (CLOSED TO ACCRUAL AS OF 9/27/2011)*]  
\_\_\_\_\_ C) CCI-779\* + Sorafenib\*\* (Patients undergoing biopsy/surgery)  
\_\_\_\_\_ D) CCI-779\* + Sorafenib\*\* (Patients not undergoing biopsy/surgery AND with prior anti-VEGF treatments)

Phase II, Arm C, and Arm D: Record dose and level

\*CCI-779: Dose = \_\_\_\_\_ mg/week; Level = \_\_\_\_\_

\*\*Sorafenib: Dose = \_\_\_\_\_ bid; Level = \_\_\_\_\_

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

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