

NORTH CENTRAL CANCER TREATMENT GROUP

Registration Eligibility Checklist

Open to Mayo Rochester, Jacksonville, Scottsdale, and University of Alabama at Birmingham only

03/28/2008

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N027D: A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

To register a patient, call (507/284-4130) or fax (507/284-0885) a completed 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

If yes: Prior study number N027D pre-registration; prior patient study ID number _____

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Pre-Reg) _____
NCCTG member (participant sponsor) _____
NCCTG treating location (chemo) _____ (RT) _____
NCCTG treating physician (chemo) _____ (RT) _____
Institution patient number (local subject number) _____
IRB approval date (chemo) (mm/dd/yyyy) ___/___/_____ IRB approval date (RT) (mm/dd/yyyy) ___/___/_____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	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
Method of payment (check one)	___ American Indian or Alaska Native
___ PI (Private Insurance)	___ Not reported: Patient refused or not available
___ MR (Medicare)	___ Unknown: Patient unsure
___ MRP (Medicare and Private Insurance)	
___ MD (Medicaid)	Ethnicity (check one)
___ MM (Medicaid and Medicare)	___ Not Hispanic or Latino
___ MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	___ Hispanic or Latino
___ MS (Military Sponsored [including CHAMPUS & TRCARE])	___ Not reported: Refused or data not available
___ MV (Veterans Sponsored)	___ Unknown: Unsure of their ethnicity
___ SP (Self pay [no insurance])	
___ NP (No means of payment [no insurance])	
___ OTH (Other)	
___ UNK (Unknown)	

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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*.

Required Characteristics

Yes No NA

Histologically confirmed GBM (grade 4 astrocytoma) by central pathology review. Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) may be included.	____	____	____
Currently not on enzyme inducing anti-convulsants (EIACs). Note: For the purpose of this study, EIAC will be defined as carbamazepine, phenytoin, or phenobarbital/primidone.	____	____	____
≥1 week and ≤6 weeks following surgical resection or biopsy. Surgical resection or biopsy date ____/____/____.	____	____	____
≥18 years. Because no dosing or adverse event data are currently available on the use of CCI-779 in patients <18 years of age, children are excluded from this study. Age = ____	____	____	____
ECOG Performance Status (PS) 0, 1, or 2.	____	____	____
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/μL. ANC = _____	____	____	____
• Hemoglobin ≥9.0 g/dL. Hemoglobin = _____	____	____	____
• PLT ≥100,000/μL. PLT = _____.	____	____	____
• Total bilirubin ≤2.5 x institutional upper limit of normal (ULN). Total bilirubin = _____; ULN = _____.	____	____	____
• Serum total cholesterol <350 mg/dL. Serum total cholesterol = _____.	____	____	____
• Serum total triglycerides <400 mg/dL. Serum total triglycerides = _____.	____	____	____
• AST (SGOT) ≤2.5 x ULN. AST (SGOT) = _____; ULN = _____.	____	____	____
• Creatinine ≤1.5 x ULN. Creatinine = _____; ULN = _____.	____	____	____
Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Women not of childbearing potential or male (<i>check NA</i>) vs. Negative serum pregnancy test date ____/____/____.	____	____	____
Ability to understand, and willingness to sign, a written informed consent.	____	____	____
Willingness and ability to comply with antibiotic prophylaxis with either trimethoprim/sulfamethoxazole (daily or 3 x per week) or monthly IV pentamidine combined with daily levofloxacin.	____	____	____
Mayo Clinic Rochester (MCR) Patients ONLY: Willingness to undergo mandatory blood tests for immune monitoring (Sections 6.34, 14.1 and 14.2). Not an MCR patient (<i>check NA</i>)	____	____	____

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

Exclusion Criteria

Yes No NA

Prior chemotherapy for any brain tumor. Prior TMZ or mTOR inhibitor therapies. Any prior cranial radiotherapy.	____	____	____
Receiving any other investigational agents.	____	____	____
Any of the following because CCI-779 has potential teratogenic or abortifacient effects based on the potential that mTOR expression is important for normal organ development: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception 	____	____	____
Other active cancers requiring therapy to control disease.	____	____	____
Major surgery (excluding neurosurgical biopsy or resection of brain tumor) or significant traumatic injury occurring ≤21 days prior to registration.	____	____	____
Gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active uncontrolled peptic ulcer disease.	____	____	____

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Patient study ID number _____

Exclusion Criteria – (continued)

Yes No NA

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.	____	____	
HIV-positive. (Note: Patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with CCI-779.)	____	____	
Any history of allergy or intolerance to Dacarbazine (DTIC).	____	____	
Patients who require warfarin (see Section 9.4).	____	____	
Severe allergy to sulfa medications and inability to tolerate either intravenous pentamidine or levofloxacin.	____	____	

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

MCR PATIENTS ONLY: A mandatory translational research component is part of this study, the patient will be automatically registered onto this component (Sections 3.29b, 14.1, 14.2). Not an MCR patient (<i>check NA</i>)	____	____	
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 ≤ 7 days after registration. Treatment may not start ≤ 6 days following a stereotactic biopsy or ≤ 13 days following an open craniotomy. Treatment start date ____/____/____.	____	____	
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/procedure date must be less than or equal to the earliest laboratory test date and the latest pretreatment test/procedure 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.	____	____	
A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	____	____	

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

Yes No NA

An optional translational research component is part of this study. There will be an option to select if the patient is to be registered onto this component (Section 14.3).	____	____	
<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 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 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 sample(s) to outside researchers. 	____	____	
Patients should be registered on NCCTG 94-72-52.	____	____	
<ul style="list-style-type: none"> • Patient will be registered on NCCTG 94-72-52 	____	____	

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

