

Registration Eligibility Checklist

03/04/2011

Page 1 of 5

N057K: Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ) Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma

Phase II patients (Mayo Clinic Rochester ONLY): 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 (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) <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
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient unsure
<input type="checkbox"/> MRP (Medicare and Private Insurance)	
<input type="checkbox"/> MD (Medicaid)	Ethnicity (check one)
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MV (Veterans Sponsored)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<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.

Inclusion Criteria

Yes No NA

Histologically confirmed GBM (grade 4 astrocytoma). Gliosarcomas and other grade 4 astrocytoma variants (e.g. giant cell) may be included. Grade 4 oligodendrogliomas or oligoastrocytomas are specifically excluded.	____	____	____
≥1 week and ≤6 weeks following surgical resection or biopsy.	____	____	____
(For Phase I patients only) Measurable disease ≥1 cm ³ . Not Phase I patient (<i>check NA</i>).	____	____	____
≥18 years of age. Because no dosing or adverse event data are currently available on the use of everolimus in patients <18 years of age, children are excluded from this study. Age = _____.	____	____	____
ECOG Performance Status (PS) of 0, 1 or 2. PS = _____.	____	____	____
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 = _____	____	____	____
• 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 pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential or male (<i>check NA</i>) vs. negative pregnancy test date ___/___/____	____	____	____
Ability to understand, and willingness to sign, a written informed consent.	____	____	____
Willingness to undergo 2 mandatory research PET or PET/CT scans. (Sections 4.2 and 6.36) PHASE I: All MCR and MCF patients PHASE II: MCR patients with measurable disease of ≥1 cm ³ . <i>Not PHASE I patient or PHASE II MCR patient with measurable disease of ≥1 cm³ (check NA).</i>	____	____	____
Willingness to provide mandatory translational research components. • Two mandatory research blood draws (Sections 6.33, 14.11) PHASE I: All MCR and MCF patients PHASE II: MCR patients only who are at MTD and undergo FLT PET • Mandatory FFPE tumor tissue blocks/slides (6.33, 17.3). PHASE I and II: All patients	____	____	____
Willingness to abstain from eating grapefruit or drinking grapefruit juice for the duration of the study.	____	____	____
Willing to follow a diet low in fat and cholesterol while taking everolimus.	____	____	____
Willingness and ability to comply with antibiotic prophylaxis with either trimethoprim/sulfamethoxazole (daily or 3 x per week), oral dapsone (daily) combined with daily levofloxacin, or monthly pentamidine (inhaled or IV) combined with daily levofloxacin.	____	____	____
Willing to have imaging scans submitted for central review. (Mandatory for patients enrolled post-Addendum 10).	____	____	____

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

Exclusion Criteria

Yes No NA

Prior chemotherapy for any brain tumor. Prior temozolomide or mTOR inhibitor therapies. Any prior cranial radiotherapy.	____	____	____
Planned immunization with attenuated live vaccines ≤7 days prior to registration and during study period. Note: Close contact with those who have received attenuated live vaccines should be avoided during treatment with everolimus. Examples of live vaccines include intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella and TY21a typhoid vaccines.	____	____	____

Patient study ID number _____

Current or prior treatment for this cancer with any other investigational agents.	_____
Currently on enzyme inducing anti-convulsants (EIACs) or other strong inducers of CYP3A4. Note: For the purpose of this study, these drugs will be defined as carbamazepine, phenytoin, phenobarbital/primidone, rifabutin, rifampin or St. John's wort.	_____
Any of the following because everolimus 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 for duration of the study and for 60 days following completion of study therapy. 	_____
Other active cancers requiring therapy to control disease, or prior cancer diagnoses, which pose a greater than 30% risk of death within the next 2 years.	_____
Major surgery (excluding neurosurgical biopsy or resection of brain tumor or treatment of immediate post neurosurgical complication, eg intracranial hematoma) 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.	_____
Uncontrolled intercurrent illness including, but not limited to the following: <ul style="list-style-type: none"> • ongoing or active infection • symptomatic congestive heart failure • unstable angina pectoris • cardiac arrhythmia • psychiatric illness/social situations that would limit compliance with study requirements • severely impaired lung function • uncontrolled diabetes as defined by fasting serum glucose >2 x ULN • any active (acute or chronic) or uncontrolled infection/ disorders. • liver disease such as cirrhosis, chronic active hepatitis, chronic persistent hepatitis or history of hepatitis B or C. 	_____
Known to be HIV-positive. Note: The mucosal adverse events of ionizing radiation in HIV-positive patients are significantly greater than in patients without HIV. Therefore, HIV-positive patients will be excluded.	_____
Any history of allergy or intolerance to Dacarbazine (DTIC).	_____
Patients who require therapeutic dose of warfarin (see Section 9.4). Note: Low molecular weight heparin is allowed. Patients who can be converted to low molecular weight heparin may enroll on the trial once they have discontinued warfarin.	_____
PHASE I (MCR and MCF ONLY): Uncontrolled diabetes that will interfere with the performance of the FDG-PET/CT or FDG-PET scans. <i>Not PHASE I (check NA).</i>	_____
Severe allergy to sulfa medications and inability to tolerate levofloxacin with dapsons or pentamidine (inhaled or IV).	_____
Positive hepatitis B antigen (HBsAg) or hepatitis C serology (HCV) tests.	_____

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

The Registration Office will automatically register patients separately to the mandatory blood (see Section 3.29a and 14.2): <ul style="list-style-type: none"> • Phase I - MCR and MCF only. <i>Not a Phase I MCR and MCF patient (check NA).</i> • Phase II – MCR only. <i>Not a Phase II MCR patient (check NA).</i> 	_____
The Registration Office will automatically register patients separately to the translational component of this study for mandatory tissue (see sections 3.29b and 17.3): <ul style="list-style-type: none"> • All patients – Phase I and II. 	_____

NCCTG Registration Eligibility Checklist N057K

03/04/2011
Page 4 of 5

Patient study ID number
Registration Check – (continued)

	Yes	No	NA
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. Note: Treatment may not start ≤6 days following a stereotactic biopsy or ≤13 days following an open craniotomy.	___	___	___
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 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.	___	___	___
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.”

The Registration Office will register patients separately to the optional translational research component of this study. The following will be recorded:	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to give tissue samples for the optional research testing. (<i>Applies to Phase I & II, MCR patients only – frozen surgical tissue from initial resection</i>). <i>Not a Phase I or II MCR patient (check NA)</i>. 	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to give future tissue samples (if available) at recurrence for the optional research testing. (<i>Applies to all patients</i>). 	___	___	___
At the time of registration/randomization, the following will also be recorded:	___	___	___
<ul style="list-style-type: none"> • Patient has given permission to collect and 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 collect and 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 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 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"> • PHASE I (MCR and MCF Only) and PHASE II (MCR Only): Patient has given permission to store MRI and PET scan discs for future research. <i>Not PHASE I or PHASE II (MCR Only) (check NA)</i> 	___	___	___
<ul style="list-style-type: none"> • PHASE II (NCCTG EXCEPT MCR): Patient has given permission to store MRI scan discs for future research. <i>Not PHASE II or PHASE II (MCR Only) (check NA)</i>. 	___	___	___
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give sample(s) to outside researchers. 	___	___	___
Patient will be registered to NCCTG 94-72-52.	___	___	___

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

Grouping Factor

Phase
 I
 II

NCCTG Registration Eligibility Checklist N057K

03/04/2011
Page 5 of 5

Patient study ID number _____

Descriptive Factors

Dose Level (to be assigned by the Randomization Center)

- 3
- 2
- 1
- 0
- 1
- 2

Registering Site (for Phase 2 only)

- MCR
- non-MCR

Assigned Treatment

A) Everolimus + RT + Temozolomide

Person registering _____

Signature

Registration Office specialist _____

initials

Physician _____

Signature

____ - ____ - ____
M D Y