

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

10/23/2009
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N0779: **Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with 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) _____

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

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 glioblastoma multiforme as determined by pre-registration central pathology review. NOTE: Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) are eligible.	____	____	____
Evidence of tumor progression by MRI or CT scan following RT or following the most recent anti-tumor therapy. NOTE: Radiographic progression soon after RT may represent altered blood-brain barrier function rather than tumor progression.	____	____	____
Bidimensionally measurable or evaluable disease by MRI or CT scan.	____	____	____
≥ 8 weeks since the completion of RT prior to registration. If no prior RT (<i>check NA</i>); If prior RT - Last day of RT ____/____/____	____	____	____
≥ 18 years of age. Age = ____	____	____	____
Fixed dose of corticosteroids (or no corticosteroids) ≥ 1 week prior to baseline scan.	____	____	____
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.	____	____	____
• WBC ≥3000/mm ³ WBC = _____	____	____	____
• ANC ≥1500/mm ³ ANC = _____	____	____	____
• PLT ≥100,000/mm ³ PLT = _____	____	____	____
• Hgb ≥9 g/dL Hgb = _____	____	____	____
• Total bilirubin ≤ 1.5 x upper normal limit (UNL) Total bilirubin = _____; UNL = _____	____	____	____
• SGOT (AST) ≤ 3 x UNL SGOT (AST) = _____; UNL = _____	____	____	____
• Creatinine ≤ UNL Creatinine = _____; UNL = _____	____	____	____
ECOG Performance Status (PS) 0, 1, or 2. PS = ____	____	____	____
Willingness to discontinue taking during this study any of the following Category I medications that are generally accepted to have a risk of causing Torsades de Pointes: <ul style="list-style-type: none"> • Quinidine, procainamide, disopyramide • Amiodarone, sotalol, ibutilide, dofetilide • Erythromycin, clarithromycin • Chlorpromazine, haloperidol, mesoridazine, thioridazine, pimozide • Cisapride, bepridil, droperidol, methadone, arsenic, chloroquine, domperidone, halofantrine, levomethadyl, pentamidine, sparfloxacin, lidoflazine 	____	____	____
Willingness to provide mandatory correlative laboratory tissue samples, as described in Section 17.3.	____	____	____
Arm A (Patients NOT undergoing surgery): ≤1 chemotherapy regimen for progressive/recurrent disease. Arm B (Patients undergoing surgery at time of recurrence): Any number of chemotherapy regimens for progressive/recurrent disease. NOTE: Adjuvant chemotherapy for all groups is allowed and does not count toward the number of regimens for progressive/recurrent disease.	____	____	____
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 ____/____/____	____	____	____
Willingness to return to an NCCTG institution for follow-up.	____	____	____

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

Patient study ID number _____

Exclusion Criteria

Yes No NA

Exclusion Criteria	Yes	No	NA
Any of the following:			
<ul style="list-style-type: none"> • ≤6 weeks since last day of nitrosourea-based chemotherapy and/or If no prior nitrosourea-based chemotherapy (<i>check NA</i>); If prior nitrosourea-based chemotherapy - Last day of prior nitrosourea-based chemo@therapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤4 weeks since last day of other chemotherapy prior to registration If no other prior chemotherapy (<i>check NA</i>) If other prior chemotherapy - Last day of other chemotherapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤2 weeks since last day of small molecule cell cycle inhibitors prior to registration If no prior small molecule cell cycle inhibitors (<i>check NA</i>); If prior small molecule cell cycle inhibitors - Last date of prior small molecule cell cycle inhibitors ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤4 weeks since last day of Avastin® prior to registration If no prior Avastin® (<i>check NA</i>); If prior Avastin® - Last day of Avastin® ___/___/_____ 	___	___	___
≤ 6 weeks since prior stereotactic radiosurgery or interstitial brachytherapy prior to registration. EXCEPTION: Separate lesion on MRI which is not part of the previous treatment field.	___	___	
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 for 6 months following the last dose of vorinostat <p>NOTE: Vorinostat and bortezomib are investigational agents whose genotoxic effects on the developing fetus and newborn are unknown.</p>	___	___	
Known hypersensitivity to any of the components of vorinostat or bortezomib.	___	___	
History of myocardial infarction or unstable angina ≤6 months prior to registration or congestive heart failure (CHF) requiring use of ongoing maintenance therapy, or history of life-threatening ventricular arrhythmias.	___	___	
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	___	___	
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.	___	___	
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 adverse events of the prescribed regimens.	___	___	
Immunocompromised patients. NOTE: Patients known to be HIV positive, but without clinical evidence of an immunocompromised state, are eligible for this trial.	___	___	
Use of valproic acid, another histone deacetylase inhibitor, for ≤ 7 days prior to registration.	___	___	
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 V for a complete list.	___	___	
≥grade 2 peripheral neuropathy due to any cause or ≥grade 1 peripheral neuropathy with pain.	___	___	
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.	___	___	
Prior treatment with vorinostat or bortezomib.	___	___	
Inability to take oral medications.	___	___	
Congenital long QT syndrome.	___	___	
Prolonged QTc interval (>450 msec).	___	___	

Patient study ID number _____

Exclusion Criteria (continued)

Yes No NA

Any of the following Category I drugs that are generally accepted to have a risk of causing Torsades de Pointes ≤ 7 days prior to registration: <ul style="list-style-type: none"> • Quinidine, procainamide, disopyramide • Amiodarone, sotalol, ibutilide, dofetilide • Erythromycin, clarithromycin • Chlorpromazine, haloperidol, mesoridazine, thioridazine, pimozide • Cisapride, bepridil, droperidol, methadone, arsenic, chloroquine, domperidone, halofantrine, levomethadyl, pentamidine, sparfloxacin, lidoflazine 	____	____	____
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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

A mandatory translational research component for tissue is part of this study; the patient will be automatically registered onto this component (Sections 3.29b and 17.0).	____	____	____
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 ≤ 14 days after registration.	____	____	____
Pretreatment tests/procedures must be completed ≤ 21 days prior to registration (see Section 4.0). NOTE: MRI date collected under “Exceptions to the above dates.” Earliest pretreatment test date ___/___/_____; latest pretreatment test date ___/___/_____	____	____	____
<u>Exceptions to the above dates:</u> <ul style="list-style-type: none"> • Hematology: WBC, ANC, PLT, Hgb and Chemistry: SGOT [AST], alkaline phosphatase, total bilirubin, sodium, potassium, glucose, calcium, creatinine obtained ≤ 14 days prior to registration (see Section 4.0, footnote 1). NOTE: The earliest hematology/chemistry test date must be less than or equal to the earliest laboratory test date and the latest hematology/chemistry test date must be greater than or equal to the latest laboratory test date. Earliest hematology/chemistry test date ___/___/_____; Latest hematology/chemistry test date ___/___/_____ • If patient was on prior Avastin®, baseline MRI needs to be ≤ 7 days prior to registration. Patient received prior Avastin®? (this question may be answered yes or no) ____ Yes. If Yes, MRI date (≤ 7 days prior to registration) ___/___/_____ ____ No. If No, MRI date (≤ 21 days prior to registration) ___/___/_____ • Patients undergoing surgery will have a post surgical MRI performed somewhere between ≥ 7 days after surgery but ≤ 28 days after surgery. 	____	____	____
All required baseline symptoms must be documented and graded.	____	____	____
Study drug 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 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 NCCTG permission to give tissue sample(s) to outside researchers.	____	____	____
• 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.	____	____	____
Patient has agreed to be enrolled on 94-72-52.	____	____	____

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

Patient study ID number _____

Grouping Factor

Arm

____ A (Patients not undergoing surgery)

____ B (Patients undergoing surgery at time of recurrence)

Subgroup code (for CTEP reporting)

____ SG1 (Patients not undergoing surgery – Patients in Arm A)

____ SG2 (Patients undergoing surgery at time of recurrence – Patients in Arm B)

Assigned Treatment

____ A) (**Patients not Undergoing Surgery**) - Vorinostat + Bortezomib

____ B) (**Patients Undergoing Surgery at Time of Recurrence**) - Vorinostat + Bortezomib

Person registering Signature _____ Registration Office specialist initials _____

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