

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist
Studies 1, 2 and 3

03/19/2010
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N0272: Phase I/II Trial of Imatinib Mesylate; (Gleevec; STI571) In Treatment of Recurrent Oligodendroglioma and Mixed Oligoastrocytoma

Study 1 only: Prior to discussing protocol entry with the patient, call the Randomization Center (507/284-4130) for dose level and to insure that a place on the protocol is open to the patient.

Has the patient ever been on a prior study entered through the Mayo/NCCTG Random. Center? Yes No

If yes: Last protocol number _____

Study reg. number _____

Registration date ____ - ____ - ____
M D Y

Patient's initials (*For Mayo-Roch Pt's: include first four letters of last name*) _____
Last, First Middle

Membership _____

Race code(s) (enter all applicable codes):
____/____/____/____/____/____

Physician _____

Ethnicity code (check one)
 Hispanic or Latino
 Non-Hispanic
 Not Reported: Pt. refused or data not available
 Unknown: Pt. is unsure of their ethnicity

Treating institution _____

Inst. pt. number _____

Gender (check one)
 Male
 Female
 Unknown

Date of birth ____ - ____ - ____
M D Y

Zip code _____ - _____

IRB approval date ____ - ____ - ____
M D Y

Method of payment _____

Country _____

Study reg. number _____

Study: (check one) ____ 1; ____ 2; ____ 3

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

Required Characteristics for Study 1:

____ ____ Currently on anticonvulsants which can induce cytochrome p450 (phenytoin, carbamazepine, barbiturates, primidone and if unsure contact study chair).
____ ____ ≤2 prior chemotherapy regimens (with maximum of 1 prior chemotherapy regimen for recurrent disease).

Required Characteristics for Study 2:

____ ____ On or off anticonvulsants.
____ ____ ≤2 prior chemotherapy regimens (with maximum of 1 prior chemotherapy regimen for recurrent disease).

Required Characteristics for Study 3:

____ ____ On or off anticonvulsants.
____ ____ >2 chemotherapy regimens or 2 prior chemotherapy regimens for progressive/recurrent disease.

Required Characteristics for Studies 1, 2, and 3:

____ ____ Age ≥18 years. Age = ____.

____ ____ Histological confirmation of a grade 2-4 oligodendroglioma, or mixed oligoastrocytoma grade 2-4 containing oligodendrogliomatous component on central pathology review prior to study registration, and a diagnosis of recurrence. Tissues from all available prior surgeries should be sent, in particular those from time of initial diagnosis.

____ ____ Measurable or evaluable disease by MRI or CT scan.

____ ____ Fixed dose of corticosteroids (or no corticosteroids) for at least 1 week prior to the pre-study baseline scan.

____ ____ Patients undergoing surgery for initial or progressive disease, must be at least 2 weeks from the date of surgery and must have recovered from the effects of their surgery, and have unequivocal tumor growth on the pre-study baseline neuroimaging study as compared to the first post-operative scan, unless there is a separate lesion or residual disease compatible with tumor that is not within the surgical bed.

____ ____ Unequivocal evidence of tumor progression by MRI or CT scan performed ≤21 days prior to study registration.

____ ____ Must have failed surgery/radiotherapy (RT) and Temozolomide or nitrosourea based therapy.

____ ____ ≥12 weeks since the completion of RT. Last day 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/mm³. ANC = _____.
- ____ ____ • PLT ≥100,000/mm³. PLT = _____.
- ____ ____ • Hgb ≥9 g/dL. Hgb = _____.

____ ____ 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.

- ____ ____ • Total bilirubin ≤1.5 mg/dL. Total bilirubin = _____.
- ____ ____ • SGOT (AST) ≤3 x Upper limit of normal (ULN).
SGOT (AST) = _____; ULN = _____.
- ____ ____ • Creatinine ≤2.0 mg/dL. Creatinine = _____.

____ ____ ECOG performance status (PS) of 0, 1, or 2.

____ ____ ≥6 weeks since the last day of nitrosourea-based chemotherapy prior to study entry.
Last day of nitrosourea-based chemotherapy ____-____-____ vs. not applicable ____.

____ ____ ≥4 weeks from any investigational agents prior to study entry.
Last day of any investigational agents ____-____-____ vs. not applicable ____.

____ ____ ≥4 weeks from other chemotherapy prior to study entry.
Last day of other chemotherapy ____-____-____ vs. not applicable ____.

____ ____ ≥2 weeks from vincristine and biologic non-cytotoxic agents e.g. tamoxifen, thalidomide, cis-retinoic acid, interferon, etc. prior to study entry.
Last day of vincristine and biologic non-cytotoxic agents ____-____-____ vs. not applicable ____.

Study reg. number _____

Eligibility Check – (Required Characteristic for Studies 1, 2 and 3: continued)

Yes No

____ ____ Patients or designated individual(s) with durable medical power of attorney for the patient must be able to provide informed, written consent, and complete any required study questionnaire(s) within the specifications of this study.

All responses in above section must be “Yes.”

Contraindications for Studies 1, 2, and 3:

- ____ ____ Receiving warfarin or heparin (see Section 9.5 for low dose warfarin).
- ____ ____ Received prior stereotactic radiosurgery, interstitial brachytherapy, or interstitial chemotherapy including BCNU wafers unless there is a separate lesion on MRI, which is not part of the previous treatment field.
- ____ ____ Active uncontrolled infection.
- ____ ____ History of myocardial infarction ≤6 months or congestive heart failure (CHF) requiring use of ongoing maintenance therapy for life-threatening ventricular arrhythmias. Patients must have a New York Heart Association (NYHA) of Class II or less. (NYHA Class I: patients with no limitation of activities; they suffer no symptoms from ordinary activities. Class II: patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion. Class III: patients with marked limitation of activity; they are comfortable only at rest. Class IV: patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest).
- ____ ____ 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 interpretation of potential drug-induced toxicities.
- ____ ____ Women of child-bearing potential, pregnant or nursing. The effects of imatinib on the developing fetus or nursing newborn are unknown, and potentially may be harmful. Such patients must have a negative pregnancy test (b-HCG) ≤7 days prior to study registration.
- ____ ____ Men or women of childbearing potential, not willing to employ adequate contraception (diaphragm, birth control pills, injections, intrauterine device [IUD], surgical sterilization, subcutaneous implants, or abstinence, etc.). The efficacy of oral contraceptives may be decreased in patients who receive p450-inducing anticonvulsants. For these patients, use of a second mode of contraception is recommended. Patients of childbearing potential must utilize effective contraception and avoid becoming pregnant or fathering a child for 6 months after completing study drug.
- ____ ____ Other active malignancy, besides skin carcinomas (must not be melanoma).
- ____ ____ Concomitant serious immunocompromised status (other than that related to concomitant steroids). Patients that are HIV positive are eligible, provided that there is no other reason for exclusion, based on the eligibility as outlined elsewhere in this section.
- ____ ____ Significant intratumoral hemorrhage on baseline MRI or CT, or other history of significant intratumoral hemorrhage.

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 M/D/Y.

Yes No

Studies 1, 2, and 3

- ____ ____ Consent form signed and dated. Date of consent ____-____-____.
- ____ ____ **Is this a USA institution?** (This question may be answered yes or no.)
 - ____ Yes → Complete authorization question below.
 - ____ No → Check “not applicable (**Non-USA institution only**)” and go to next question.
- ____ ____ Authorization for use and disclosure of protected health information signed and dated.
- ____ ____ Authorization for use and disclosure of protected health information signed and dated.
- ____ ____ Date of authorization ____-____-____ vs. not applicable (Non-U.S.A. institution only) ____.
- ____ ____ Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.

Study reg. number _____

Registration Check – (continued for studies 1, 2, and 3)

Yes No

____ ____ Treatment cannot begin prior to registration and must begin ≤7 days after registration.
____ ____ History and exam, wt., PS; Height; Neuro history and exam; Linear Analogue Self Assessment (LASA); Hematology; Head MRI or CT with contrast; Chest x-ray; ECG; Recording of steroid dose; and Anticonvulsant level 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.

Exceptions to the above dates:

- Chemistry obtained ≤7 days prior to registration (see Section 4.0).
Chemistry test date ____-____-____.
- Serum pregnancy test, for women of childbearing potential only, must be done ≤7 days prior to registration and every four weeks during treatment (see Section 4.0).
Serum pregnancy test date ____-____-____ vs. not done ____.
If serum pregnancy test not done, reason: _____.

____ ____ All required baseline symptoms must be documented and graded on the on-study form.
____ ____ Study drug availability checked.

All responses in above section must be “Yes.”

Randomization Center will register patients separately to the translational research component of this study (Studies 1 and 2 patients only) (see Section 14.0).

- ____ ____ • Patient has given permission to give blood sample for research testing.
- ____ ____ • Patient has given permission to give tissue sample for research testing.

Studies 1, 2, and 3: The following will also be recorded:

- ____ ____ Patient has given permission to store and use blood sample for future research of cancer.
- ____ ____ Patient has given permission to store and use tissue sample for future research of cancer.
- ____ ____ Patient has given permission to store blood sample for future research to learn, prevent, or treat other health problems.
- ____ ____ Patient has given permission to store tissue sample for future research to learn, prevent, or treat other health problems.
- ____ ____ Patient has given NCCTG permission to give their blood sample to outside researchers.
- ____ ____ Patient has given NCCTG permission to give their tissue sample to outside researchers.

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

Grouping Factor

Study (See Appendix IIIB for list of EIAC and non-EIAC agents.)

N/A 2 - EIAC (Arm A will not open until a dose level has been established in Study 1)

____ 2 - Non EIAC

____ 1

N/A 3 - EIAC (Arm D will not open until a dose level has been established in Study 1)

____ 3 - Non-EIAC

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Descriptive Factors (for studies 1, 2, and 3)

Age (Years)	ECOG Performance Score (PS)	Prior nitrosoureas
<input type="checkbox"/> <40	<input type="checkbox"/> 0	<input type="checkbox"/> Yes
<input type="checkbox"/> 40-60	<input type="checkbox"/> 1	<input type="checkbox"/> No
<input type="checkbox"/> >60	<input type="checkbox"/> 2	

Interval since end of RT (months): _____ Corticosteroid therapy at study entry
 Yes
 No

Family history of brain tumor
 Yes (check all that apply)
 Father
 Mother
 Brother/Sister
 Child
 Other (list: _____)
 No

Number of prior chemotherapy regimens: _____

Assigned Treatment

- N/A A) Study 2: Imatinib (EAC patients) (**Arm A will not open until a dose level has been established in Study 1**)
 B) Study 2: Imatinib (Non-EIAC patients)
 C) Study 1: Imatinib*
 N/A D) Study 3: Imatinib (EAC patients) (**Arm D will not open until a dose level has been established in Study 1**)
 E) Study 3: Imatinib (Non-EIAC patients)

*Imatinib: Dose = _____ Daily Total Dose; Level = _____

Person registering Signature _____ Registration Office specialist initials _____

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