

NORTH CENTRAL CANCER TREATMENT GROUP
NCCTG REGISTRATION (STEP 2) ELIGIBILITY CHECKLIST N078D

02/05/2010
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N078D: Phase I/II Trial of Rituximab, Cladribine, and Temozolomide (RCT) Therapy in Newly Diagnosed Mantle Cell Lymphoma (MCL).

Phase I patients only: 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.

Phase II patients only: To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

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.)

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*.

Registration - Inclusion Criteria

Yes No NA

Histologically confirmed MCL. The diagnosis must be confirmed by NCCTG pre-registration pathology review by Dr. Paul Kurtin or his designate (see Section 17.1). It is recommended that the biopsy be an excisional biopsy, but adequate core-needle biopsies will be accepted as long as they are considered adequate for registration by Dr. Kurtin or his designate. The tumor must be cyclin D-1 positive by immunohistochemistry or have evidence of a t(11;14) translocation by FISH or cytogenetics.	____	____	____
Measurable or assessable disease defined as at least one of the following: <ul style="list-style-type: none"> A lymph node or tumor mass that is ≥ 2.0 cm in at least one dimension by PET/CT, CT, MRI, or plain radiograph imaging. Splenic enlargement may be used as a measurable parameter if the spleen is palpable ≥ 3 cm below the left costal margin. Diffuse infiltration of an organ such as the stomach, bone marrow, peripheral blood, liver, lungs, or bowel by lymphoma without a discrete mass would constitute assessable, but not measurable, disease. 	____	____	____
≥ 18 years of age. Age = _____	____	____	____
ECOG performance status (PS) of 0, 1, 2, or 3. Performance Status = _____.	____	____	____
Life expectancy ≥ 12 weeks.	____	____	____
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.	____	____	____
<ul style="list-style-type: none"> ANC ≥ 1500 ANC = _____ 	____	____	____
<ul style="list-style-type: none"> PLT $\geq 100,000$ PLT = _____ 	____	____	____
The following laboratory values obtained ≤ 28 days prior to registration: Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
<ul style="list-style-type: none"> Serum creatinine ≤ 2.0 mg/dL Serum Creatinine = _____ 	____	____	____
<ul style="list-style-type: none"> Serum total bilirubin (or direct bilirubin if total is abnormal) \leq institutional upper limit of normal (ULN) with or without secondary liver involvement. Is total bilirubin $>ULN$? (this question may be answered yes or no) ____ Yes \rightarrow Direct bilirubin = _____ ____ No \rightarrow Total bilirubin = _____; ULN = _____ 	____	____	____
<ul style="list-style-type: none"> SGOT ≤ 3 x institutional ULN (exception: if there is liver involvement, SGOT must be ≤ 5 x institutional ULN.) Liver involvement? (This question may be answered "Yes" or "No") ____ Yes. \rightarrow(SGOT ≤ 5 x institutional ULN) SGOT = _____; ULN = _____. ____ No. \rightarrow(SGOT ≤ 3 x institutional ULN) SGOT = _____; ULN = _____. 	____	____	____
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 NCCTG enrolling institution for follow-up.	____	____	____
Willingness to provide the blood specimens as required by the protocol (see Sections 6.33 and 14.1).	____	____	____
Willingness to provide tissue specimens as required by the protocol (see Sections 6.34 and 17.1).	____	____	____
Willingness to abstain from eating grapefruit or drinking grapefruit juice for the duration of the study.	____	____	____

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

Patient study ID number _____

Registration - Exclusion Criteria

Yes No NA

Any prior therapy for mantle cell non-Hodgkin lymphoma including radiation therapy. <u>Exception:</u> Patient may have undergone a splenectomy for diagnosis, cytopenia, or systematic splenomegaly.	___	___	
Active or uncontrolled infection.	___	___	
Any of the following cardiac conditions: <ul style="list-style-type: none"> • Uncontrolled high blood pressure • Unstable angina • Active congestive heart failure • Myocardial infarction ≤6 months • Serious uncontrolled cardiac arrhythmia 	___	___	
Known CNS involvement.	___	___	
Any of the following because this study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown: <ul style="list-style-type: none"> • Pregnant women or women of reproductive ability who are unwilling to use effective contraception while taking the drug and for 12 months after stopping treatment. • Nursing women • Men who are unwilling to use a condom (even if they have undergone a prior vasectomy) while having intercourse with any woman, while taking the drug and for 12 months after stopping treatment. 	___	___	
Medical or psychiatric conditions which, in the opinion of the investigator, make the patient a poor risk for participation.	___	___	
Known to be HIV positive. HIV testing is not required but should be done if clinically indicated. HIV patients are excluded because of concerns regarding excess risk of complications of immunosuppressive therapy regimens. HIV-positive patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with temsirolimus.	___	___	
Concurrent malignancy ≤5 years ago. Exceptions: carcinoma in situ of the cervix, resected basal cell or squamous cell carcinomas of the skin, or prostate cancer that is in remission following a radical retropubic prostatectomy or radiation therapy. If there is a history of prior malignancy, they must not be receiving other specific treatment (other than hormonal therapy) for their cancer.	___	___	
Known hypersensitivity to rituximab or its components, or to murine proteins.	___	___	
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.	___	___	
Prior treatment with an mTOR inhibitor.	___	___	
Autologous or allogeneic stem cell transplant planned as part of initial therapy.	___	___	
Receiving enzyme-inducing antiepileptic drugs (EIAEDs; e.g., phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, or primidone); any other potent CYP3A4 inducer such as rifampin, glucocorticoids at greater than adrenal replacement levels, or St. John's wort; or receiving strong CYP3A4 inhibitors. Note: See Appendix II for a more complete list of drugs which may interact with temsirolimus metabolism. Note: If these agents are discontinued, temsirolimus therapy can begin ≥7 days after discontinuation of such agent.	___	___	

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 blood translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.29b and 14.1).	___	___	
A mandatory tissue translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.29c and 17.1)	___	___	
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 ≤10 days after registration.	___	___	

Patient study ID number _____

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

Pretreatment tests/procedures (see Section 4.0) must be completed ≤14 days prior to registration. 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.	____	____	
<u>Exceptions to the above dates:</u> Exception pretreatment tests can be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test date ___/___/____; latest exception test date ___/___/____.	____	____	
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	
Study drug availability checked.	____	____	
Blood draw kit availability checked.	____	____	

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

At the time of registration/randomization, the following will also be recorded:			
• 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 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 NCCTG permission to give blood sample(s) to outside researchers.	____	____	
• 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 agreed to be enrolled on N0392.	____	____	

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

Grouping Factor:

- ____ Phase I
- ____ Phase II (includes patients treated at MTD in Phase I)

Descriptive Factor

Dose Level (to be assigned by the Registration Office):

- ____ Dose Level 1
- ____ Dose Level 2
- ____ Dose Level 3
- ____ Dose Level 4
- ____ Dose Level 5

Assigned Treatment

____ A) 2-CDA + RITUX + CCI779*

*Temsirolimus: Dose = _____ mg/d

Person registering Signature _____ Registration Office specialist initials _____

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