

Eligibility Checklist

N0682: A Phase II Clinical Trial of Denileukin Diftitox in Combination with Rituximab in Previously Untreated Follicular B-cell Non-Hodgkin's Lymphoma.

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 Randomization Center? Yes No

If yes: Last protocol number _____; previous patient ID number _____

Patient study ID number _____	Registration date (date on) (mm/dd/yyyy) ___/___/_____
NCCTG member (participant sponsor) _____	
NCCTG treating location _____	
NCCTG treating physician _____	
Institution patient number (local subject number) _____	
IRB approval date (mm/dd/yyyy) ___/___/_____	

Patients initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply) <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Not reported: Patient refused or not available <input type="checkbox"/> Unknown: Patient unsure
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	
Date of birth (mm/dd/yyyy) ___/___/_____	
Zip code _____	
Country of Residence _____	
Method of payment (check one) <input type="checkbox"/> PI (Private Insurance) <input type="checkbox"/> MR (Medicare) <input type="checkbox"/> MRP (Medicare and Private Insurance) <input type="checkbox"/> MD (Medicaid) <input type="checkbox"/> MM (Medicaid and Medicare) <input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS)) <input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE]) <input type="checkbox"/> MV (Veterans Sponsored) <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)	Ethnicity (check one) <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not reported: Refused or data not available <input type="checkbox"/> 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

Follicular grade 1 or 2 B-cell non-Hodgkin's lymphoma. The diagnosis must be confirmed by NCCTG pre-registration pathology review (See section 17.2 and 18.1).	_____	_____	_____
Willingness to provide translational research components (Section 6.23). <ul style="list-style-type: none"> • Research blood draws (Section 14.2). • FFPE tumor tissue blocks/slides submitted prior to registration (Section 17.3). 	_____	_____	_____
Previously untreated for NHL (no prior chemotherapy, immunotherapy, vaccines or radiation therapy for NHL). Stage III or IV.	_____	_____	_____
≥ 18 years of age. Age = _____.	_____	_____	_____
Must have measurable disease defined as at least one lesion whose longest diameter can be accurately measured as ≥ 20 mm (i.e. ≥2 cm). See Section 11.0 for the evaluation of measurable disease. Measurable masses (such as enlarged lymph nodes) must have a clearly defined bidimensional diameter of at least 2 x 2 cm on physical examination or ≥ 2.0 cm in one of the dimensions by 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.	_____	_____	_____
ECOG Performance Status 0, 1, or 2. ECOG 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.	_____	_____	_____
• WBC ≥ 3400 x 10 ⁶ cells/L. WBC = _____.	_____	_____	_____
• PLT ≥ 100,000 x 10 ⁶ /L. PLT = _____.	_____	_____	_____
• HgB ≥ 10.0 g/dL. HgB = _____.	_____	_____	_____
• Total bilirubin ≤ 1.5 x institutional upper normal limit (UNL). Total bilirubin = _____; UNL = _____.	_____	_____	_____
• Alkaline phosphatase ≤ 3 x UNL. Alkaline phosphatase = _____; UNL = _____.	_____	_____	_____
• AST ≤ 3 x UNL. AST = _____; UNL = _____.	_____	_____	_____
• Creatinine ≤ 1.5 x UNL. Creatinine = _____; UNL = _____.	_____	_____	_____
• Albumin ≥ 3 g/dl. Albumin = _____.	_____	_____	_____
Negative serum pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (<i>check NA</i>) vs. negative pregnancy test date ____/____/____.	_____	_____	_____
Life expectancy of ≥ 1 year.	_____	_____	_____

All responses in above section must be "Yes."

Registration - Contraindications

Yes No NA

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 methods during the study. The immunologic effects of denileukin diftitox and rituximab may be harmful to a developing fetus or nursing infant. Denileukin diftitox has potential toxicities and the developing fetus is felt to be at risk if these toxicities occur.	_____	_____	_____
≥ 5000 circulating tumor cells per microliter.	_____	_____	_____
Central nervous system (CNS) lymphoma.	_____	_____	_____

Patient study ID number _____

Registration – Contraindications continued

Yes No

HIV infection. We anticipate that treatment with rituximab and denileukin diftitox will suppress intratumoral regulatory T-cells and reverse the inhibition of the antitumor immune response. Patients with HIV infection will be excluded from the study as they are generally immune suppressed by the HIV infection and are unlikely to respond to this strategy.	
Active malignancies other than lymphoma.	
Presence of active uncontrolled infection.	
Known hypersensitivity to denileukin diftitox or any of its components: diphtheria toxin, interleukin-2, or excipients.	

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 mm/dd/yyyy.

Yes No NA

A mandatory translational research component is part of this study. The patient will be automatically registered onto this component (Section 3.22, 14.2 and 17.3).	
Prior to accepting the registration, the application will verify the following: • Patient eligibility	
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	
Treatment cannot begin prior to registration (if not done at pre-registration) and must begin ≤14 days after registration.	
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.	
<u>Exceptions to the above dates:</u> Exception pretreatment test/procedures can be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test/procedure date ___/___/____; latest exception test/procedure 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.”

Patient study ID number _____

Registration Check –continued

At the time of registration, the following will also be recorded:	
<ul style="list-style-type: none"> • Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat cancer. 	____ _
<ul style="list-style-type: none"> • Patient has given permission to store and use blood sample(s) for 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 store and use tissue sample(s) for future research to learn about, prevent, or treat cancer. 	____ _
<ul style="list-style-type: none"> • Patient has given permission to store and use 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"> • Patient has given NCCTG permission to give samples(s) to outside researchers. 	____ _
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 17.4).	
<ul style="list-style-type: none"> • Patient has given permission to give fresh tumor tissue sample for optional research testing. 	____ _
Patient has agreed to be enrolled on N0392 (N0392 must be open at site and offered to patient).	____ _

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

Assigned Treatment Arm

_____ A) RITUX + ONTAK

Person registering _____ Random. specialist _____
 Signature initials

Physician _____ M - D - Y
 Signature