

North Central Cancer Treatment Group

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

Addendum 1– June 13, 2008

**Summary**

- Remote registration has been incorporated into Section 6.0.
- Administrative/Editorial changes.

**A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol**

**Title page** Updated NCI version date and addition of Addendum 1 have been added.

**Protocol Resource Page**

Page 2: Mary Beth Wilwerding's contact information has been revised with addition of phone extension and e-mail address.

Helen Tollefson has been removed as a "paraffin-embedded tissue pathology" contact. Christine Maszk remains as a contact.

Jacqueline Lafky's fax number has been revised. It is now (507) **266-0824**.

**Section 3.0 Patient Eligibility**

Page 8: The first bullet in Section 3.22 has been revised as follows for clarification:

- Research blood draws ~~prior to registration~~

**Section 6.0 Registration/Randomization Procedures**

Pages 12/13: The method of registration has changed from calling in registration to remote registration. Because of large amount of text, repagination from this point forward.

The following has been revised (only affecting 6.11, 6.13, and 6.22):

~~6.11 To pre-register a patient, call (507)284 4130 or fax (507/284 0885) a completed Step 1 eligibility checklist to the Registration Office between the hours of 8 a.m. and 4:30 p.m. Central Time Monday through Friday.~~

- ~~At the time of pre-registration the patient will receive an NCCTG patient identification number. This number is to be used when submitting tissue or blood samples (See Section 14.0 and 17.0).~~

6.11 To pre-register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application. The remote registration/randomization application is available 24 hours a day, 7 days a week. Back up and/or system support contact information is available on the Web site. If unable to access the Web site, call the NCCTG Registration Office at (507)-284-4130 between the hours of 8 a.m. and 4:30 p.m. Central Time (Monday through Friday).

The instructions for remote registration are available on the NCCTG web page and detail the process for completing and confirming patient pre-registration. Users should refer to the section titled “Pre-Registration Components” for details on how to pre-register a patient to a study. At the time of pre-registration the patient will receive an NCCTG patient identification number. This number is to be used when submitting tissue or blood samples (See Sections 14.0 and/or 17.0). Patient pre-registration via the remote system can be confirmed in any of the following ways:

- Contact the NCCTG Registration Office at (507)-284-4130. If the patient was pre-registered, the Registration Office staff can access the information from the centralized database and confirm the pre-registration.
- Refer to “Instructions for Remote Registration” in section “Finding/Displaying Information about A Registered Subject.”

6.13 Prior to accepting the pre-registration, the Registration Office Personnel ~~Application~~ will verify the following:

- IRB approval at the registering institution
- **Patient eligibility**
- Existence of a signed consent form
- Existence of a signed authorization for use and disclosure of protected health information (*U.S.A. institutions only*)

6.22 ~~To register a patient, call (507/284 4130) or fax (507/284 0885) a completed Step 2 eligibility checklist to the Registration Office between the hours of 8 a.m. and 4:30 p.m. Central Time Monday through Friday~~ To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application. The remote registration/randomization application is available 24 hours a day, 7 days a week. Back up and/or system support contact information is available on the Web site. If unable to access the Web site, call the NCCTG Registration Office at (507) 284-4130 between the hours of 8 a.m. and 4:30 p.m. Central Time (Monday through Friday).

The instructions for remote registration are available on the NCCTG web page and detail the process for completing and confirming patient registration. Users should refer to the section titled “Pre-Registration Components” for details on how to register a pre-registered patient to a study. Prior to initiation of protocol treatment, this process must be completed in its entirety and a NCCTG subject ID number must be available as noted in the instructions. It is the responsibility of the individual and institution registering the patient to confirm the process has been successfully completed prior to release of the study agent. Patient registration via the remote system can be confirmed in any of the following ways:

- Contact the NCCTG Registration Office at (507)-284-4130. If the patient was fully registered, the Registration Office staff can access the information from the centralized database and confirm the registration.
- Refer to “Instructions for Remote Registration” in section “Finding/Displaying Information about a Registered Subject.”

Page 14: Section 6.29a have been revised for clarification as follows:  
 6.29a Patient **has/has not agreed to** ~~should~~ be enrolled on ~~QOL~~ N0392 (N0392 must be open at site and offered to patient)  
 • ~~Patient will/will not be enrolled on N0392.~~

#### **Section 14.0 Body Fluid Biospecimens**

Page 30: The second sentence in Section 14.452 has been revised for clarification as follows:  
 Cytotoxicity of PBMC effectors toward lymphoma cells will be performed on specimens obtained at baseline, every 3 weeks on treatment (**i.e. Day 1 Cycles 2-4**) and 1 month and 4 months after completing treatment.

The first sentence in Section 14.462 has been revised for clarification as follows:  
 To further assess immune activation after treatment with rituximab and denileukin diftitox, we will measure the plasma levels of a variety of inflammatory cytokines at baseline, every 3 weeks on treatment (**i.e. Day 1 Cycles 2-4**) and 1 month and 4 months after completing treatment using a multiplex ELISA.

#### **Section 15.0 Drug Information**

Page 35: In Section 15.254, the adverse risk of “dehydration” was duplicated, so the second occurrence was removed.

**Section 17.0 Pathology Considerations/Tissue Biospecimens**

Page 47: Text has been added to Section 17.38 at the beginning of the paragraph as follows:  
**Upon appropriate request approval,** the NCCTG Operations Office will forward the block/slides to Dr. Stephen M. Ansell's Hematology Research laboratory, Stable 6-13 (phone: 4-3805), Mayo Clinic Rochester for

**Section 19.0 Budget**

Page 53: Section 19.3 has been revised for clarification as follows:

- ... ~~The translational research listed in section 14.0~~ **Optional biopsy: Reimbursement for a standard needle biopsy** will be funded by the Lymphoma SPORE Grant (CA097274-06P4).
- ... **Translational research studies listed in section 14.0 will be funded by Eisai, Inc.**