BMT CTN 0202 Version 4.0 (1/17/2006)

Autologous vs. Non-Myeloablative Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Patients with Chemosensitive Follicular Non-Hodgkin's Lymphoma Beyond First Complete Response or First Partial Response

Significant Changes to Version 3.0 of the Protocol

- An initial patient eligibility criterion in *§2.3.1 Initial Patient Eligibility Criteria* was revised to include patients with histologically confirmed WHO classification follicular lymphoma grades 1, 2, 3a, or 3b, in addition to patients with REAL classification grades I and II. For either classification, the diffuse component or presence of large cleaved cells (if present) cannot be > 50% of high power field.

- An initial patient eligibility criterion in *§2.3.1 Initial Patient Eligibility Criteria* was revised to expand the definition of chemosensitive disease to include a $\geq$ 50% reduction in estimated lymph node volume, a change from a > 75% reduction.

- Dosing of tacrolimus will be based on IBW for patients who weigh 100-120% of their IBW; based on ABW for patients who weigh less than 100% of their IBW; and based on AIBW for patients who weigh more than 120% of their IBW. This is reflected in *§2.7.2 Body Weight Formulas* and in *§2.7.5.2 Graft versus host disease (GVHD) prophylaxis*.

Changes to Patient Consent

- The following wording was added to *§19 How will my information be kept private*:

  Information related to or resulting from your stem cell transplant will be reported to the Center for International Blood and Marrow Transplant Research (CIBMTR). The CIBMTR is a voluntary organization of basic and clinical scientists working together in an effort to gather information on results of stem cell and marrow transplants. This information is used to guide clinical decisions and identify ways to improve transplant outcomes. Scientific data or medical information (not identifiable with you) that could be useful to others may be presented at meetings and/or published in medical journals.

- Southwest Oncology Group has been added to the list of groups who have the legal right to review patient research records in *§19 How will my information be kept private?* Only SWOG-participating centers are required to add this group to the patient consent.

- Southwest Oncology Group has been added to the list of parties who may use patients' health information in *§22 HIPAA authorization to use and disclose individual health information for research purposes.* Only SWOG-participating centers are required to add this group to the patient consent.

Change to Donor Consent

- Southwest Oncology Group has been added to the list of parties who may use donors' health information in *§22 HIPAA authorization to use and disclose individual health information for research purposes.* Only SWOG-participating centers are required to add this group to the donor consent.

Minor Changes to Version 3.0 of the Protocol

- The number of patients to be enrolled has been corrected to 80 patients with an HLA-matched sibling and 187-320 patients without an HLA-matched sibling. This is reflected in the Protocol Synopsis, *§5.2.1 Accrual,* and *§5.3 Sample Size and Power Calculation.*

- Rituximab will be mixed in either 0.9% NS or D5W according to institutional practice. This is reflected in *§2.7.3.2 Cyclosphosphamide and rituximab administration/mobilization, §2.7.4.3 Rituximab maintenance therapy,* and *§2.7.5.1 Conditioning regimen.*

- It was clarified that rituximab, BCNU, VP-16, fludarabine, and cyclophosphamide dosing is based on IBW for patients who weigh 100-120% of their IBW; based on ABW for patients who weigh less than 100% of their IBW; and based on AIBW for patients who weigh more than 120% of their IBW. This is reflected in *§2.7.3.2 Cyclophosphamide and rituximab administration/mobilization, §2.7.4.1 Conditioning regimen – chemotherapy-based regimen, §2.7.4.2 Conditioning regimen – total body irradiation-based regimen,* and *§2.7.5.1 Conditioning regimen.*

- SWOG patient registration procedures were added to *§4.1.1 Screening and Eligibility Procedures and §4.1.2 SWOG Patient Registration Procedures.*

- In *Table 4.2.1 Follow-up Schedule – Segment A,* the window around the target dates has been expanded to ± 7 days prior to day 100 post transplant.

- It was clarified in *§4.2.4.1 Evaluations prior to rituximab and cyclophosphamide* and *Table 4.2.4.8.a Baseline, Pre-HSCT, Donor Evaluations* that the baseline quantitative PCR analysis of t(14;18) must be done after enrollment.

- A chest x-ray is no longer required prior to initiation of the HSCT conditioning therapy. This is reflected in *§4.2.4.3 Evaluations prior to the autologous or non-myeloablative allogeneic HSCT* and *Table 4.2.4.8a Baseline, Pre-HSCT, Donor Evaluations.*

- A sub-group analysis of grade 3 follicular lymphomas was added to *§5.5.1 Analysis of the Primary Endpoint.*

- *§6 Polymerase Chain Reaction (PCR),* Appendix C, was corrected to indicate that the PCR samples that are shipped to the repository are to be collected in lavender top vacutainers.

- The table, *Schedule of Laboratory Evaluation*, Appendix C, was corrected to indicate that the donor and patient nucleated cell research specimens and the non-baseline PCR samples are to be stored at –150 C.

<u>Administrative Changes to Version 3.0 of the Protocol</u>

- Marcie Tomblyn, M.D. has been added to the protocol team.

- The list of participating centers has been modified.