BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK

BMT CTN PROTOCOL #0201

A Phase III Randomized, Multicenter Trial Comparing G-CSF Mobilized Peripheral Blood Stem Cell with Marrow Transplantation from HLA Compatible Unrelated Donors

Major Changes/Clarifications to Version 8.0 of the Protocol:

Chapter 2

- In §2.6.2, modified the GVHD prophylaxis to allow for multiple regimens rather than just the previously specified two regimens. Specifically the section now states:

2.6.2 GVHD Prophylaxis Regimen

The choice of GVHD prophylaxis regimen is by institutional preference. Any regimen or protocol may be used, with the exception that Phase I GVHD prophylaxis protocols are not allowed. The regimen and dosing employed must not be dependent on graft source assignment, i.e., marrow or PBSC.

The two most commonly used GVHD prophylaxis regimens following unrelated donor transplantation are:

1. Cyclosporine/methotrexate
2. Tacrolimus/methotrexate

The recommended doses and schedule of administration of cyclosporine, tacrolimus and methotrexate are as detailed in Sections 2.6.3 and 2.6.4. This information is provided only as a guideline.

Alternative or additional agents/dosing may be used per institutional preference. However, the use of Phase I agents is prohibited.

The transplant center will declare before randomization what GVHD prophylaxis regimen will be used for that particular patient. The declared regimen must be used whether the patient is randomized to receive PBSC or marrow. There is no requirement for the institution to use the same regimen for each subsequent patient enrolled.

Minor Changes/Clarifications to Version 8.0 of the Protocol:

Synopsis

- Modified Treatment Description to state: "The GVHD prophylaxis regimen will be per institutional standard, but may not contain any Phase I agents."

Appendix B

- Modified all the recipient consent form and legal guardian consent form attachments to include the following:"***If other agents are used for GVHD prophylaxis then analogous paragraphs describing risks of those agents must be added to your version of the consent form."***