BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK

BMT CTN 0901
A Randomized, Multi-Center, Phase III Study of Allogeneic Stem Cell Transplantation Comparing Regimen Intensity in Patients with MDS or AML

Modifications to Version 4.0 of the Protocol

Deletions to the Protocol and Informed Consent are indicated in strike-out text; additions are noted in underlined text. The significant updates include: (1) distinguishing HLA-match requirements for sibling versus relative other than sibling and (2) clarification that bone marrow biopsy/aspirates are required for disease testing at Day 100 and 18 months and that peripheral blood or bone marrow samples are required for chimerism at Day 28, Day 100 and 18 months.

***§Protocol Synopsis, Eligibility Criteria**:* **…**and an available related or unrelated bone marrow or peripheral blood donor. ~~Related donor must be a 7/8 or 8/8 match at HLA-A, -B, -C, (serologic typing or higher resolution) and –DRB1 (at high resolution using DNA-based typing)~~. Sibling donor must be a 6/6 match at HLA–A and –B (intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing). Related donor other than sibling must be a 7/8 or 8/8 match for HLA–A, –B, –C (at intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing). Unrelated donor must be a 7/8 or 8/8 match at HLA-A, -B, -C and –DRB1 at high resolution using DNA-based typing….

§2.3.1 Inclusion Criteria #4: Patients must have a related or unrelated bone marrow or peripheral blood donor: ~~(a) Related donor must be a 7/8 or 8/8 match at HLA-A, -B, -C, (serologic typing or higher resolution) and –DRB1 (at high resolution using DNA-based typing)~~; (a) Sibling donor must be a 6/6 match at HLA–A and –B (intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing); (b) Related donor other than sibling must be a 7/8 or 8/8 match for HLA–A, –B, –C (at intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing); (c) Unrelated donor must be a 7/8 or 8/8 match at HLA-A, -B, -C, and -DRB1 at high resolution using DNA based typing.

§4.3.3.1 Pre-transplant evaluations #7: ~~For related donors, HLA typing at HLA-A, -B, -C, using serologic typing (or higher resolution) and –DRB1 using high resolution DNA-based typing~~. For sibling donors, HLA typing at HLA–A and –B (intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing). For related donors other than a sibling, HLA–A, –B, –C (at intermediate or higher resolution) and –DRB1 (at high resolution using DNA-based typing). For unrelated donors, HLA typing at HLA-A, -B, -C, and –DRB1 at high resolution using DNA-based typing if not already performed.

§4.3.3.2 Post-transplant evaluations #5: Blood or bone marrow aspirate sample for post-transplant T-cell and myeloid chimerism assay collected at Day 28, 100, and 18 months. Whole bone marrow chimerism is an acceptable alternative if lineage-specific chimerism analysis is not available. Peripheral blood chimerism can be substituted for bone marrow chimerism if bone marrow sample is not available.

Table 4.3 Summary of Patient Clinical Assessments: Blood or Bone Marrow for Myeloid and T-cell Chimerism is required at ~~baseline~~, Day 28, 100, and 18 months

Appendix B, Informed Consent

- *§Before You Start Your Treatment* (page B-6): Chest x-ray ~~and EKG~~;
- *§Study Evaluations* (page B-7): Bone marrow biopsy and/or aspirate at-Day ~~28,~~ 100 and 18 months.