



## BMT CTN PROTOCOL #0402

### **A Phase III Randomized, Multicenter Trial Comparing Sirolimus/Tacrolimus with Tacrolimus/Methotrexate as Graft-Versus-Host Disease (GVHD) Prophylaxis After HLA-Matched, Related Peripheral Blood Stem Cell Transplantation**

Deletions to the protocol are indicated in strike-out text; additions are noted in underlined text.

#### **Clarifications to Version 3.0 of the Protocol:**

- §2.3.1.3 *Patient Eligibility for Randomization*

Acute Biphenotypic Leukemia at the following stages:

- First Remission
- Second or subsequent remission

Complete remission is defined as the absence of blasts in the peripheral circulation at the time of enrollment and < 5% blasts in the marrow within 28 days of enrollment.

- §*Table 4.6b Patient Clinical Assessments*: The table was updated to reflect that whole blood samples should be collected at Day 730 (and not at Day 270)

#### **Clarifications to Version 3.0 of the Participant Informed Consent:**

§*About Using Blood for Research (page B-11)*: If you agree, these samples will be obtained at the time other blood samples are drawn on 6 occasions pre-transplant and on Day 28, 100, 180, ~~270 and 365~~ and 730.