PROTOCOL SYNOPSIS PROTOCOL #1001-34
Comparison of BMT CTN #0303 Study Result to an AML Subset of BMT CTN #0101 as an Historical Control

Primary Objective: The primary objective of this protocol is to compare the results from the BMT CTN #0303 study (CD34 Selection of Mobilized Donor Peripheral Blood Cells with CliniMACS® CD34 Reagent System) to a contemporary historical control in patients with acute myelogenous leukemia (AML) undergoing allogeneic transplantation from HLA matched sibling donors. For the purposes of this comparison, AML CR1 and CR2 patients from the BMT CTN #0101 trial will be used to provide the contemporary cohort of patients.

The focus of this analysis will be to support the hypothesis that T cell depletion via CD34 selection as the sole form of immune suppression (BMT CTN #0303) is safe compared to conventional GVHD prophylaxis post transplant (BMT CTN #0101) for patients with AML in CR1 and CR2 with respect to the incidence and severity of acute GVHD and chronic GVHD without compromising, engraftment, transplant-related mortality, relapse rate, disease free and overall survival.

Study Design: The analysis is planned as a prospective comparison of retrospective data from the BMT CTN #0101 Fungal Prophylaxis trial titled "A Randomized Double-blind Trial of Fluconazole vs. Voriconazole for the Prevention of Invasive Fungal Infections in Allogenic Blood and Marrow Transplant Patients" and the BMT CTN #0303 trial titled "A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, $CD34^+$ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS® System in the Treatment of Patients with AML in First or Second Morphologic Complete Remission." As the comparison was not pre-specified in the BMT CTN #0303 Study, the data analysis will be conducted under this Analysis Protocol. Details concerning selection of control cases from BMT CTN #0101 are provided in Section 4.1 of this document.

Eligibility Criteria: The eligibility criteria for the BMT CTN #0303 Study required patients from 18 to 65 years of age with AML in first or second morphologic complete remission with an HLA-identical sibling donor. A similar subset of patients will be analyzed from the BMT CTN #0101 Study (see Section 4.1).

Treatment Description: Treatment for the patients included in the BMT CTN #0101 and #0303 studies are described in the individual protocols and summarized in the following Protocol Synopses.