

# A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source In Matched Sibling Donor Transplantation (COG ASCT0631 PBMTCT SCT051)

IRB# 2008-006

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## Synopsis:

ASCT0631 is a Phase III trial comparing two graft sources for allogeneic transplantation using HLA identical siblings as donors: bone marrow and filgrastim (G-CSF) stimulated bone marrow (G-BM) in children undergoing allogeneic transplantation for leukemia's in which matched sibling donor transplantation is appropriate. The protocol is designed to implement a novel strategy to integrate transplant questions into treatment studies in the cooperative group setting, allowing patients on disease specific treatment protocols co-enrollment on a study designed to investigate a transplant-specific question in a manner which does not adversely impact the primary, disease specific, treatment question. Thus, there will be two categories of leukemia patients enrolled on ASCT0631 – those for whom ASCT0631 is the only study enrollment, and those who are also enrolled on ASCT0431, AAML0532, or other leukemia treatment studies. The major hypothesis of this protocol is that the increased bone marrow cell dose provided by the graft collected on the G-BM arm of this study will improve the event-free survival of these patients. We further hypothesize that patients on the G-BM arm will show more rapid engraftment kinetics with equivalent rates of acute and lower rates of chronic graft vs. host disease. Any patient with acute or chronic leukemia or myelodysplasia needing bone marrow transplantation with a matched sibling donor available is eligible for this study. Eligible diseases include AML in CR1 or CR2; myelodysplastic syndrome; ALL in CR2 or high-risk CR1; CML in first or second chronic phase and JMML. G-BM will be collected from donors on the experimental arm after five days of G-CSF treatment of the donor. Target volume for both BM and G-BM collections is 15 cc/kg of recipient weight, with a maximum of 20 cc/kg donor weight. Biological studies will correlate graft characteristics with the incidence of GVHD and measure the rate of immunologic recovery of the patients. We will also assess the experience of the donor and family during participation on this protocol. There will be collection of acute adverse donor events and long-term donor experience using the national standard RDSafe approach pioneered by the NMDP and CIBMTR/NMDP.