BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK

BMT CTN PROTOCOL #0403

A Phase III Randomized Double-Blind, Placebo-Controlled Trial of Soluble Tumor Necrosis Factor Receptor: Enbrel (Etanercept) for the Treatment of Acute Non-Infectious Pulmonary Dysfunction (Idiopathic Pneumonia Syndrome) Following Allogeneic Cell Transplantation.

Major Changes to Version 4.0 of the Protocol:

- *§ Chapter 5* – The study design was revised to reflect the reduction in sample size from 120 patients (60 per arm) to 60 patients (30 per arm). Planned interim analyses for efficacy were removed from the protocol, but the monitoring of key safety endpoints will continue to be conducted on a monthly basis. The synopsis and Chapter 5 have been amended to reflect the revised sample size.

Minor Changes to Version 4.0 of the Protocol:

- *§* Section 2.7.2. Corticosteroids (Day 0-28): Arm A and Arm B (new text in *italics*): All patients are required to be on methylprednisolone (or corticosteroid equivalent) at 2 mg/kg/day on Day 0 of study therapy. Corticosteroids shall be administered in divided doses, BID. ~~Corticosteroids should be administered by intravenous (IV) route for the first three days of therapy, then changed to oral (PO) dosing if the patient is able to tolerate oral intake.~~ *While it is preferred that corticosteroids be administered by IV for the first 7 days of study enrollment, they may be given orally (PO) if deemed appropriate.* If initially given IV, corticosteroids can later be changed to PO dosing when the patient is able to tolerate oral intake. Corticosteroid dosing should be based upon actual body weight.

Changes to Version 4.0 of the Participant Informed Consent:

§ The informed consent document was updated to reflect the new sample size of 60 patients (30 per arm).