PROTOCOL SYNOPSIS – BMT CTN 0702 LONG-TERM FOLLOW-UP PROTOCOL

Continued, Long-Term Follow-Up and Lenalidomide Maintenance Therapy for Patients Who Have Enrolled on BMT CTN 0702

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Study Design: The study is designed to provide continued, long-term follow-up on patients enrolled on BMT CTN 0702 who have not experienced progression, as well as to offer optional long-term lenalidomide maintenance therapy to those BMT CTN 0702 patients who have completed 3 years of protocol-defined maintenance therapy without evidence of disease progression.

Primary Objective: The primary objective is to compare progression-free survival (PFS) as a time to event analysis between the three randomized treatment arms from the BMT CTN 0702 protocol as a pairwise comparison. The analysis will be conducted once all surviving patients have been followed for at least 5-years post randomization on the BMT CTN 0702 protocol.

Secondary Objectives: Secondary objectives include the cumulative incidence of second primary malignancies (SPM), probability of overall survival (OS), probability of event-free survival (EFS) and Health Quality of Life (QOL) on all patients, including those not receiving long-term lenalidomide maintenance therapy.

Eligibility Criteria: Patients eligible for long-term follow-up are those who were enrolled and randomized on the BMT CTN 0702 protocol and who are alive at the end of the BMT CTN 0702 protocol-defined follow-up period without progression. Patients eligible for long-term lenalidomide maintenance therapy include patients who have completed 3 years of BMT CTN 0702 protocol-defined lenalidomide maintenance therapy with no evidence of disease progression.

Treatment/Follow-Up: All patients who consent to the long-term follow-up protocol will undergo study assessments every 6-months. Patients eligible to continue with lenalidomide maintenance therapy will continue with the last tolerated dose of lenalidomide that was documented upon completion of BMT CTN 0702 maintenance therapy.

Accrual Objective:	It is anticipated that approximately 450 patients will be enrolled on this protocol based on assumed estimates of PFS from the BMT CTN 0702 study. The total sample size may be as low as 417 if the observed 3-year PFS on the BMT CTN 0702 is 55% but may be as high as 569 if the 3-year PFS is 75%.
Study Duration:	Patients will be followed until death, progression, withdrawal from the study, or through the end of 2018.
Interim Analysis:	No formal interim analyses are planned.

Figure 1: Study Schema

Outline of Study Schema for Long-Term Follow-Up and Lenalidomide Maintenance