PROTOCOL SYNOPSIS - BMT CTN 1902

Phase II Multicenter Trial of anti-B Cell Maturation Antigen Chimeric Antigen Receptor T Cell Therapy for Multiple Myeloma Patients with Sub-Optimal Response After Autologous Hematopoietic Cell Transplantation and Maintenance Lenalidomide

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Study Design: This study is designed as a Phase II, multicenter, single arm trial to assess anti-B Cell Maturation Antigen (BCMA) chimeric antigen receptor (CAR) T-cells (bb2121) to improve post autologous hematopoietic cell transplant (HCT) responses among patients with multiple myeloma (MM).

Primary Objectives: The primary objective is to evaluate the efficacy of BCMA CAR T cell therapy to improve the response in patients who received an upfront autologous HCT and lenalidomide maintenance.

Secondary Objectives: The secondary objectives include assessment of disease progression, response to treatment as determined by improved response and conversion to minimal residual disease (MRD) negativity, non-relapse mortality, progression free survival (PFS), incidence of cytokine release syndrome (CRS), incidence of prolonged cytopenias, and incidence of neurotoxicity

Exploratory Objectives: Exploratory objectives to be described include incidence of toxicities greater than or equal to grade 3 per the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, incidence of infections per protocol-specific Manual of Procedures (MOP), maintenance feasibility, overall survival, disease response, CAR T-cell expansion, CAR T-cell persistence, BCMA expression, immune reconstitution

Eligibility Criteria: Eligible patients are greater than or equal to 18.00 and less than 71.00 years of age with MM with less than a very good partial response (VGPR) within 12 months after an autologous HCT with melphalan > 140mg/m^2, have initiated lenalidomide maintenance at least 6 months ago, and have not experienced disease progression since initiation of initial systemic anti-myeloma therapy.

Treatment Description: After meeting the eligibility criteria and enrolling on the trial, patients will undergo leukapheresis for collection of autologous lymphocytes, which will be sent to BMS/Celgene manufacturing facilities. Once cells have been manufactured, patients will then proceed to lymphodepleting chemotherapy with cyclophosphamide 300mg/m^2 and fludarabine 30mg/m^2 for 3 consecutive days followed by the infusion of BCMA CAR T-cells at a target dose of 450 x10^6 cells. Maintenance lenalidomide, starting at 10mg a day for 21 days of a 28-day cycle will be initiated at a minimum of at least 30 days, but no later than 180 days after the CAR T-cell infusion and will

	continue until the patient reaches 12 months post CAR T-cell infusion and continue free of progression.
Accrual Objective:	40 patients
Accrual Period:	22 months
Target Number of Sites:	15 sites
Study Duration:	Patients will be followed for 12 months after bb2121 infusion
Long Term Follow Up:	All patients will be followed for 15 years to meet regulatory requirements through a long term follow up protocol using the CIBMTR infrastructure.

BMT CTN 1902 STUDY SCHEMA