Adoptive Transfer of Autologous T Cells Targeted to Prostate Specific Membrane Antigen (PSMA) for the Treatment of Castrate Metastatic Prostate Cancer (CMPC)

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Abstract

Rationale: Expression of prostate-specific membrane antigen (PSMA) in prostate cancer confers a survival advantage to the tumor cells, but strongly enhances T cell recognition and cytolysis. The ability of Ab-targeted T cells to cause tumor regression is strongly dependent on the ability of the Ab to induce T cell activation and cytolytic function. This is a Phase I dose-escalating trial designed to assess the safety, tolerability, and preliminary efficacy of autologous T cells transduced with a novel PSMA-directed CAR and administered immediately following treatment with cyclophosphamide (Cy). The main objectives of this clinical trial are: (1) to assess the safety, tolerability, and preliminary efficacy of the PSMA-directed CAR transduced autologous T cell therapy in patients with metastatic prostate cancer, and (2) to assess the feasibility of achieving PSMA expression with Cy treatment.

Objectives: The objectives of this clinical trial are to (1) assess the safety, tolerability, and preliminary efficacy of the PSMA-directed CAR transduced autologous T cell therapy in patients with metastatic prostate cancer, and (2) to assess the feasibility of achieving PSMA expression with Cy treatment.

Methods: Patients will be treated with Cy on the day prior to receiving autologous targeted T cells. This is primarily a dose-escalating trial designed to assess the safety, tolerability, and preliminary efficacy of the PSMA-directed CAR transduced autologous T cell therapy in patients with metastatic prostate cancer. The next day, patients will be admitted to the MSKCC GU inpatient service for leukapheresis.

Conclusion: The next day, patients will be admitted to the MSKCC GU inpatient service for leukapheresis.