NORTHSIDE HOSPITAL CANCER INSTITUTE

BLOOD & MARROW TRANSPLANT PROGRAM

NSH C-459 PHASE II Clinical Trial Opening

Administration of HIV-specific T cells to HIV+ Lymphoma Patients Receiving High Dose Chemotherapy Followed by Autologous Stem Cell Rescue - Auto-RESIST

The Blood and Marrow Transplant Program at Northside Hospital in collaboration with The Blood and Marrow Clinical Trials Network (BMT CTN) is conducting a Phase II multi-center trial single-arm trial of autologous transplantation (ASCT) followed by administration of HIV antigen-specific T-cells Targeting Conserved Epitopes (HST-NEETs) for treatment of HIV associated lymphoma.

Objectives

Primary Objectives

- The proportion of participants who can be treated with HST-NEETs within one (1) week of autologous hematopoietic stem cell transplantation (ASCT).
- The efficacy of HST-NEETs in reducing the HIV intact proviral reservoir at 6 months after ASCT.

Secondary Objectives

- Progression-free survival at six (6) months and 1-year post-ASCT.
- The incidence and severity of acute infusion-related toxicities.
- The impact of therapy on the HIV intact proviral reservoir at 1-year post-ASCT.

Inclusion Criteria

- Age ≥15 years old at time of enrollment.
- Receiving antiretroviral therapies (ART) with HIV viral load below the limit of detection by standard commercial assay.
- Diagnosis of refractory or recurrent diffuse large B-cell lymphoma, composite lymphoma with greater than 50% diffuse large B-cell lymphoma, mediastinal B-cell lymphoma, immunoblastic, plasmablastic, Burkitt or high-grade B-cell lymphoma or classical Hodgkin lymphoma.
- Two or three prior regimens of chemotherapy over the entire course of their disease treatment (induction chemotherapy and salvage chemotherapies).

Exclusion Criteria

- Karnofsky performance score < 70%.
- Participant is known to have an HIV subtype other than B.
- Participant has documented raltegravir or protease inhibitor resistance.
- Uncontrolled bacterial, viral or fungal infection (currently taking medication and with progression or no clinical improvement).
- Prior autologous or allogeneic HCT or prior therapy with chimeric antigen receptor (CAR) T-cells.

If you have any questions, would like to discuss study logistics, or the eligibility of any patients, please contact:
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