NORTHSIDE HOSPITAL
CANCER INSTITUTE
BLOOD & MARROW
TRANSPLANT PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

Blood & Marrow Transplant Program

PHASE 1 Clinical Trial Opening

NSH 1173

A Phase I Study of Donor BPX-501 T-Cell Infusion for Adults with Recurrent or Minimal Residual Disease Hematologic Malignancies Post-Allogeneic Transplant

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NH BMT in collaboration with Bellicum is offering a phase I, open-label, non-randomized study of BPX-501 T-cell infusion in adults with hematological malignancies presenting with recurrent disease ≥100 days post-allogeneic transplant or minimal residual disease (MRD) ≥30 days post-allogeneic transplant.

Donor lymphocyte infusion (DLI) is used after stem cell transplant (SCT) to treat and prevent relapse, to prevent infections, and to establish full donor chimerism. Adding mature T cells might increase the risk of developing acute GVHD. The use of a suicide gene switch with the ability to trigger initiation of apoptosis of the alloreactive T cells when exposed to an agent of choice would function as a "safety switch" against GVHD side effects.

BPX-501 contains genetically modified donor T cells that have an inducible safety switch iCasp9 suicide gene. Administration of Rimiducid dimerizing agent activates capase 9, which subsequently activates downstream caspases thereby obligating cellular apoptosis within 24 hours. This mechanism offers an effective means to safely manage BPX-501 T cell therapy.

Three courses of BPX-501 are given at 30-day intervals with 2 escalating dose levels. Two doses of Rimiducid (AP1903) will be given for treatment of GVHD.

INCLUSION CRITERIA

RECIPIENT
- Age 18-65
- Leukemia, MDS, lymphomas, MM, other high-risk malignancies
- Recurrent disease @ ≥100 days or MRD @ ≥30 days post-TP
- >25% donor chimerism

DONOR
- Donor of most recent allo TP
- Age 18-60
- Adequate peripheral venous access or agrees to catheter placement

EXCLUSION CRITERIA

RECIPIENT
- ≥Grade II aGVHD or cGVHD extensive exposure
- Active CNS involvement
- Bovine product allergy

DONOR
- Evidence of active infection or viral hepatitis

If you have any questions, would like to discuss study logistics, or the eligibility of any patients, please contact Stacey Brown, NH BMT/Leukemia Clinical Research Manager, at **404-851-8238** or **stacey.brown@northside.com**.

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