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 1170

A Multicenter, Open-Label Study of JCAR017, CD19-Targeted Chimeric Antigen Receptor (CAR) T Cells, in Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL)

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Northside BMT/Leukemia programs in collaboration with Juno Therapeutics is offering a Phase I clinical trial utilizing JCAR017. The JCAR017 investigational drug product is comprised of autologous CD4+ and CD8+ T cells that are genetically engineered to express CD19-specific CARs. The CAR is expressed on the T cell surface and redirects the T cells to CD19-expressing lymphoma cells, leading to CD19-specific tumor cell recognition, lysis, cytokine secretion and T cell proliferation.

PRE-TREATMENT PHASE:
A leukapheresis collection will be performed on each subject to obtain a sufficient quantity of peripheral blood mononuclear cells (PBMCs) for the production of the JCAR017 investigational product at the Juno manufacturing facility.

TREATMENT PHASE:
- A treatment cycle will include chemotherapy with flu/cy followed by one (single-dose schedule) dose of JCAR017 administered intravenously (IV).
- JCAR017 will be administered 2 to 7 days after completion of chemotherapy.
- Multiple cycles of JCAR017 treatment, consisting of chemotherapy followed by 1 or 2 doses of JCAR017, will be allowed for subjects who have not reached a CR to similarly attempt to enhance antitumor activity.
- After treatment with JCAR017, subjects will be monitored closely for 28 days.
- Day 29, subjects will enter a post-treatment follow-up, and will be followed on this study for safety, disease progression, and survival for 2 years after their last dose of JCAR017.
- After the 2 years, subjects will followed on a separate protocol for 15 years, as required by the FDA for any subject that received a biologic product.

Time Period during JCAR017 Manufacturing Prior to Chemotherapy Administration:
- Anticancer treatment is allowed for disease control while JCAR017 is being produced (i.e., after leukapheresis and prior to chemotherapy).
- Some medications are prohibited and washout prior to dosing may be required.

INCLUSION CRITERIA
- ECOG between 0 and 1
- Relapsed or refractory B-cell NHL or Mantle Cell Lymphoma (MCL)
- Previous treatment of at least 2 lines of therapy or 1 line in MCL or after auto HSCT
- Archived tumor biopsy tissue available from the last relapse and corresponding pathology report available for disease confirmation , and willing to undergo pre- and post-treatment biopsy if at least one tumor-involved site is deemed accessible at time of screening

EXCLUSION CRITERIA
- Subjects with central nervous system (CNS)-only involvement by malignancy (note: subjects with secondary CNS involvement are allowed on study)
- Active acute or chronic GVHD
- Prior malignancy < 2 years
- Active hepatitis B, hepatitis C, or HIV

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**.

NORTHSIDE HOSPITAL
CANCER INSTITUTE
5670 Peachtree Dunwoody Road
Suite 1000
Atlanta, GA 30342