NORTHSIDE HOSPITAL
CANCER INSTITUTE
LEUKEMIA PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

Leukemia Program

PHASE 1 Clinical Trial Opening

NSH 1165

Phase 1 Dose-escalation Study to Evaluate the Tolerability, Safety, Pharmacokinetics, and Antitumor Activity of ADCT-402 in Patients with Relapsed or Refractory B-cell Lineage Non Hodgkin Lymphoma (B-NHL)

northside.com/BMTprogram | bmtga.com

In collaboration with ADCT Therapeutics, the NSH-BMT Program is participating in a Phase 1, open-label, dose escalation (Part 1) and expansion (Part 2) study of the safety and tolerability of ADCT-402, used as monotherapy, in patients with relapsed or refractory B-cell NHL. ADCT-402 is an antibody drug conjugate (ADC) composed of a humanized monoclonal antibody, directed against human CD19.

STUDY DESIGN

Patients will receive a 1-hour IV infusion of ADCT-402, on Day 1 of each 21-day cycle.

In Part 1, patients will be assigned to treatment according to a 3+3 dose escalation design.

In Part 2, (expansion), all patients will be assigned to the dose level of ADCT-402 identified in Part 1.

INCLUSION CRITERIA

Ages 18 or older with pathologically-confirmed relapsed or refractory B-cell lineage NHL who have failed or are intolerant to established therapy, or for whom no other treatment options are available, in the opinion of the Investigator. Patients must have measurable disease.

Eligible diseases include:

- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma (FL)
- Chronic lymphocytic leukemia (CLL)
- Mantle cell lymphoma (MCL)
- Marginal Zone B-cell Lymphoma (MZBCL)
- Burkitt's lymphoma (BL)
- Lymphoplasmacytic lymphoma (Waldenstrom macroglobulinemia [WM]).

EXCLUSION CRITERIA

- Patients who, in the opinion of the Investigator, have any option for other treatment for B-cell NHL at the current state of disease.
- Active graft-versus-host disease.
- Autologous or allogeneic transplant within the 60 days prior to the Screening visit.
- Known history of immunogenicity or hypersensitivity to a CD19 antibody.
- Evidence of myelodysplasia or myeloid leukemia by morphology, immunostains, flow cytometry, or cytogenetics on a bone marrow aspirate or biopsy.

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