NORTHSIDE HOSPITAL
CANCER INSTITUTE
LEUKEMIA PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

Leukemia Program

PHASE 1 Clinical Trial Opening

C250

A Phase 1, Open-label, Dose-escalation, Multicenter Study to Evaluate the Tolerability, Safety, Pharmacokinetics and Activity of ADCT-301 in Patients with Relapsed or Refractory CD25-positive Acute Myeloid Leukemia or CD25-positive Acute Lymphoblastic Leukemia.

northside.com/leukemia | bmtga.com

NHCI Leukemia Program in collaboration with ADCT Therapeutics is offering a phase 1, open-label, dose escalation (Part 1) and expansion (Part 2) of the safety and tolerability of ADCT-301, used as monotherapy, in patients with relapsed or refractory CD25-positive AML or ALL. The study will determine the MTD, as well as evaluate the preliminary activity, PK and PD of ADCT-301.

ADCT-301 is an antibody drug conjugate (ADC), composed of the human monoclonal antibody, HuMax-TAC, directed against CD25, and conjugated through a cleavable linker to SG3199, a pyrrolobenzodiazepine (PBD) dimer cytotoxin. After binding to the cell surface and internalization, ADCT-301 is transported to the lysosomes, where the protease sensitive linker is cleaved and free PBD dimers are released inside the target cell.

STUDY OBJECTIVES

- Evaluate the safety and tolerability and determine the maximum tolerated dose (MTD) of ADCT-301 in patients with CD25-positive relapsed or refractory AML or CD25-positive ALL. (Part 1).
- Determine the recommended dose of ADCT-301 for Part 2.
- Evaluate the safety and tolerability of ADCT-301 in Part 2 at dose level recommended in Part 1.

Patient MUST be CD25 positive to be considered for this clinical research trial.

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