NORTHSIDE HOSPITAL
CANCER INSTITUTE
LEUKEMIA PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

Leukemia Program

PHASE 1 Clinical Trial Opening

NSH 1164

A Phase 1 Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb®14045 in Patients with CD123-Expressing Hematological Malignancies

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In collaboration with Xencor, NSH-BMT Program is participating in a multicenter, open label, multiple dose Phase 1 dose escalation study of XmAb14045 and will serve as the first-in-human (FIH) study. XmAb14045 is an antibody that binds both CD3, tumor antigen CD123, and recruits cytotoxic T cells that can kill CD123+ tumor cells.

This study is designed in two parts: Part A, dosing cohorts that establish a Maximum Tolerated Dose (MTD)/Recommended Dose (RD) for the first infusion; and Part B, dosing cohorts that establish a MTD/RD for the second (and subsequent infusions) after patients receive their first infusion at the dose determined in Part A.

INCLUSION CRITERIA

- Age ≥ 18 years
- Diagnosis of 1 of the following diseases:
  - Primary or secondary AML (including erythroleukemia and eosinophilic leukemia, but excluding acute promyelocytic leukemia)
  - B-Cell ALL
  - BPDCN
  - CML in blast phase, resistant or intolerant to tyrosine kinase nhibitor therapy
- Patients with relapsed or refractory disease with no available standard therapy. For AML, this includes patients with:
  - Newly diagnosed leukemia refractory to ≥ 2 induction attempts
  - Leukemia in first relapse with initial CR duration of < 6 months
  - Leukemia in first relapse following ≥ 1 unsuccessful salvage attempts, or
  - Leukemia in second or higher relapse
- Not a candidate for, or refusing HSCT

EXCLUSION CRITERIA

- Cytotoxic chemotherapy, radiotherapy, immunotherapy or investigational product treatment within 2 weeks of the first dose of study drug WBC ≥ 10,000/mm3 or symptoms of leukocytosis (Hydroxyurea or other therapies may be used to control leukocytosis through the first month of study therapy)

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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