NORTHSIDE HOSPITAL CANCER INSTITUTE

IMMUNOTHERAPY PROGRAM

NH1325 PHASE I Clinical Trial

Phase I, open label, multicenter, dose escalation study of YTB323 in adult patients **with CLL/SLL, DLBCL and ALL**

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Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Novartis is participating in a Phase I, open label, multicenter, dose escalation study of YTB323. The study is currently enrolling to two treatment arms:

- YTB323 single agent in adult DLBCL patients having failed two or more lines of chemotherapy and either having progressed (or relapsed) after autologous HSCT, or being ineligible for or not consenting to the procedure.
- YTB323 single agent in adult relapsed/refractory ALL patients.

Primary Objectives:

- Identify the recommended dose of YTB323.
- Characterize safety of YTB323 as single agent in DLBCL and relapsed/refractory adult ALL.

Secondary Objectives:

- To assess antitumor activity of YTB323 single agent in relapsed/refractory adult ALL as assessed by CR/CRi rate by 3 months.

Inclusion Criteria

DLBCL Arm:

- Relapsed or refractory disease having received 2 or more lines of systemic therapy, including anti-CD20 and anthracycline-based

chemotherapy, and either having progressed (or relapsed) after autologous HSCT, or being ineligible for or not consenting to the procedure.

ALL Arm:
Refractory or relapsed CD19-positive ALL including at least one of the following:

- After allogeneic HSCT
- After 2 or more lines of treatment
- Primary refractory disease
- First relapse occurring within 12 months from first remission
- Patients with Philadelphia chromosome-positive ALL must have failed at least 2 different tyrosine kinase inhibitors or are intolerant.

Exclusion Criteria

- Prior CD19-directed therapy with the exception of blinatumomab for patients with ALL
- Prior administration of a genetically modified cellular product
- Primary Central Nervous System (CNS) lymphoma or DLBCL with active CNS involvement, except if CNS involvement has been effectively treated and provided that treatment was > 4 weeks before screening. For ALL: presence of CNS-2 disease with neurological changes or CNS-3 disease.

If you have any questions, would like to discuss study logistics, or the eligibility of any patients, please contact Caitlin Guzowski, NH BMT/Leukemia Clinical Research Manager, at **404-851-8523** or Caitlin.Guzowski@northside.com