

NSH 1251


NORTHSIDE HOSPITAL
CANCER INSTITUTE


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IMMUNOTHERAPY PROGRAM

The Blood & Marrow
Transplant Group
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PHASE I Clinical Trial Opening

For Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma Patients

Northside Hospital Cancer Institute Immunotherapy Program in collaboration with Juno/Bristol Myers Squibb, is opening a Phase 1, first-in-human, open-label, multi-center study of CC-97540, CD19-targeted NEX-T chimeric antigen receptor (CAR) T-cells, in subjects with relapsed or refractory B-cell non-Hodgkin lymphoma.

 **BUILT TO BEAT CANCER**

Objectives

- To evaluate CC-97540 safety and tolerability.
- To determine the maximum tolerated dose of CC-97540.
- To evaluate antitumor activity.
- To determine the recommended Phase II dose of CC-97540.

Inclusion Criteria

Relapsed or refractory aggressive B-cell non-Hodgkin lymphoma as defined:

- Histologically confirmed DLBCL not otherwise specified, high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements with DLBCL histology (HGBCL), transformed DLBCL from follicular (tFL) or marginal zone lymphoma (tMZL), primary mediastinal B-cell lymphoma (PMBCL), or FL grade 3b (FL3B). (Swerdlow, 2016)

AND

- Have relapsed and/or refractory disease after at least two lines of systemic therapy which must include at least one anthracycline and rituximab (or other anti-CD20 monoclonal antibody).

Note: Lines of therapy will exclude those given for prior indolent lymphoma. It is not required for subjects to have had anthracycline for their DLBCL if received for indolent disease.

AND/OR

- Have relapsed and/or refractory DLBCL failed to autologous stem cell transplant treatment. Autologous stem cell transplant failure is defined as either failure to achieve an objective response (partial response or better), or disease progression after autologous stem cell transplant.

Exclusion Criteria

- CNS only involvement. Pathologically confirmed secondary CNS involvement IS allowed.
- No prior CD19 targeted therapy.

*ClinicalTrials.gov Identifier: NCT03483103



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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 **404-780-7965** or **stacey.brown@northside.com**.