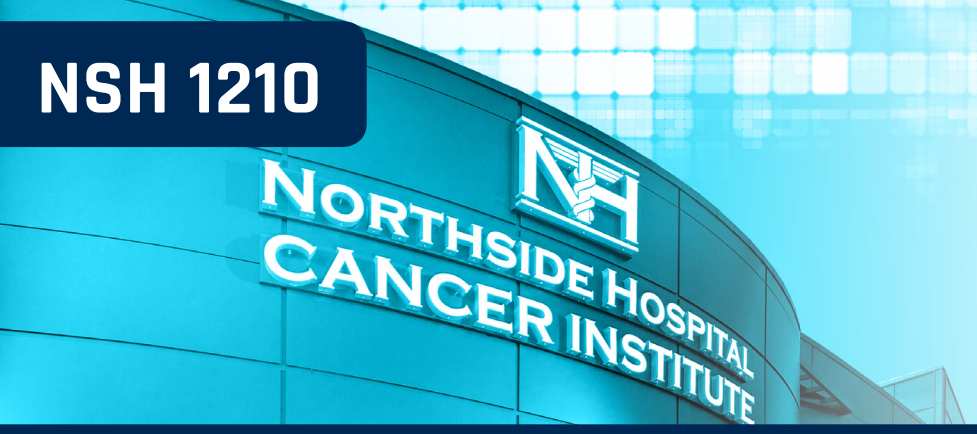
NSH 1210



NORTHSIDE HOSPITAL
CANCER INSTITUTE
IMMUNOTHERAPY PROGRAM

The Blood & Marrow Transplant Group
OF GEORGIA

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PHASE II Clinical Trial Opening

For Relapsed/Refractory Diffuse Large B-Cell Lymphoma Patients

Northside Hospital Cancer Institute Immunotherapy Program is opening a Phase II, multi-center, open-label, single-arm study sponsored by ADC Therapeutics to evaluate Human CD19 antigen, a 95 kd transmembrane glycoprotein belonging to the immunoglobulin superfamily, for patients with relapsed/refractory DLBL. Loncastuximab tesirine (ADCT-402) is an antibody drug conjugate (ADC) designed to target and kill CD19-expressing malignant B-cells.

PRIMARY OBJECTIVE: Evaluate the efficacy of single agent loncastuximab tesirine in patients with relapsed or refractory DLBCL.

TREATMENT: Loncastuximab tesirine will be administered once every three weeks for up to one year until no longer receiving clinical benefit, disease progression or unacceptable toxicity.

BUILT TO BEAT CANCER

CRITERIA

Inclusion	Exclusion
• Relapsed or refractory DLBCL following two or more multi-agent systemic treatment regimens DLBC NOS, primary mediastinal, high grade B-cell with MYC and BCL2 and/or BCL6 rearrangement is eligible • Patients who have received previous CD19-directed therapy must have a biopsy that shows CD19 protein expression after completion of the CD19-directed therapy • Measurable disease as defined by the 2014 Lugano Classification • Availability of formalin-fixed paraffin-embedded (FFPE) tumor tissue block (or minimum 10 freshly cut unstained slides if block is not available) • ECOG performance status 0-2	• Previous treatment with loncastuximab tesirine • Known history of hypersensitivity to or positive serum human ADA to a CD19 antibody • Pathologic diagnosis of Burkitt lymphoma • Active second primary malignancy other than non-melanoma skin cancers, non-metastatic prostate cancer, in situ cervical cancer, ductal or lobular carcinoma in situ of the breast, or other malignancy that the Sponsor's medical monitor and Investigator agree • Autologous stem cell transplant within 30 days prior to start of drug • Allogeneic stem cell transplant within 60 days prior to start of drug • Active graft-versus-host disease • Post-transplant lymphoproliferative disorders • Lymphoma with active CNS involvement • Major surgery, radiotherapy, chemotherapy, or other anti-neoplastic therapy within 14 days prior to start of study drug • QTcF interval of >480 ms

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**.

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