

NSH 1207

**NORTHSIDE HOSPITAL
CANCER INSTITUTE**



**NORTHSIDE HOSPITAL
CANCER INSTITUTE**
IMMUNOTHERAPY PROGRAM

**The Blood & Marrow
Transplant Group**
O F G E O R G I A

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PHASE III **Clinical Trial Opening**

For Patients with High Risk, Transplant-Eligible Relapsed/Refractory Aggressive B-cell Non-Hodgkin's Lymphomas (TRANSFORM)

Northside Hospital Cancer Institute in collaboration with Celgene is offering a randomized, open-label, parallel-group, multi-center, Phase III study to demonstrate the efficacy and safety of JCAR017 versus SOC salvage therapies in subjects with aggressive B-cell NHL, diffuse large B-cell lymphoma (DLBCL) NOS (de novo or transformed indolent NHL), high grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements with DLBCL histology (double/triple-hit lymphoma [DHL/THL]), primary mediastinal (thymic) large B-cell lymphoma (PMBCL), T cell/histiocyte-rich large B-cell lymphoma (THRBCL) or follicular lymphoma grade 3B (FL3B) who are refractory to front line immunochemotherapy or have relapsed within 12 months and are eligible for HDCT and HSCT.

BUILT TO BEAT CANCER

Primary Objective

To compare the efficacy in subjects treated with JCAR017 versus subjects treated according to standard of care (SOC) defined as event-free survival (EFS)

Key Inclusion Criteria

- Age \geq 18 years and \leq 75 at the time of consent
- ECOG PS \leq 1
- Relapsed or refractory B-cell NHL
- Refractory (SD, PD, PR or CR with relapse before 3 months) or relapsed (CR with relapse on or after 3 months) within 12 months from CD20 antibody and anthracycline containing first line therapy
- Must have PET positive lesion(s) at screening
- Enough tumor material must be available for confirmation by central pathology
- Secondary CNS involvement is acceptable

Key Exclusion Criteria

- Subjects not eligible for HSCT
- Previous CD19-targeted therapy
- Planned allogeneic HSCT
- Prior malignancy resolved \leq 2 years
- Treatment with prior gene therapy
- History/Active hepatitis B, hepatitis C, or HIV

* ClinicalTrials.gov Identifier: NCT03575351


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5670 Peachtree Dunwoody Road
Suite 1000
Atlanta, GA 30342

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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**.