



**NORTHSIDE HOSPITAL
CANCER INSTITUTE**

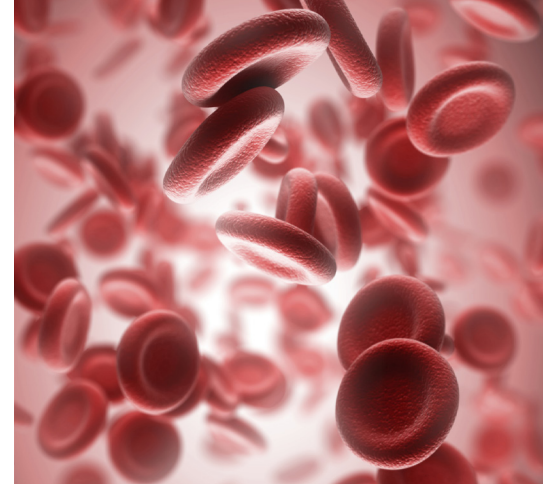
BLOOD & MARROW TRANSPLANT
PROGRAM

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



**NORTHSIDE HOSPITAL
CANCER INSTITUTE**

LEUKEMIA PROGRAM



Novel Acute Myeloid Leukemia Immunotherapy BMT Clinical Research Trial

.....

Clinical Trial Opening

Open to Enrollment: NSH 1150 Phase II Trial of Lymphodepletion and Anti-PD-1 Blockade to Reduce Relapse in High Risk AML Patients Who Are Not Eligible for Allogeneic Stem Cell Transplantation

The NH-BMT program is enrolling high-risk acute myeloid leukemia (AML) patients who are not eligible for allogeneic transplant onto this cutting edge immunotherapy clinical research trial. AML is the most common acute leukemia in adults. Some patients with AML are not candidates for allogeneic transplantation due to age, overall health, psychosocial factors, and/or lack of an available donor. This single center study is designed to stimulate anti-leukemic immunity within the host in order to promote immune-mediated elimination of AML and hopefully break immune tolerance to AML cells to provide better outcomes in patients with non-favorable risk AML.

- All patients will receive an autologous transplant using Fludarabine and Melphalan.
- Pembrolizumab begins on Day +1 and continues over 24 weeks for a total of 8 doses.

ELIGIBILITY CRITERIA

Inclusion:

- 18-78 years of age
- Non-favorable risk AML
 1. Poor risk cytogenetics
 2. Intermediate-risk cytogenetics with non-favorable molecular testing
 3. CBF AML associated with C-kit mutation
- Completed 1 cycle of consolidation chemo with no residual disease by morphology, flow, cytogenetics or FISH
- In CR1 or subsequent CR
- Collection of at least 2×10^6 /kg CD34+ cells
- Adequate lab values

Exclusion:

- Not eligible for an allogeneic stem cell transplant
- Received investigational agents within 4 weeks of first dose
- Prior chemo or radiation therapy within 2 weeks of first dose
- Uncontrolled infection
- History of active TB
- Received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent
- Received live vaccine within 30 days of first dose

If you should have any questions, would like to discuss study logistics, or the eligibility of any patents, please contact Stacey Brown, NH-BMT/Leukemia clinical research manager, at 404-851-8238 or stacey.brown@northside.com.



NORTHSIDE HOSPITAL CANCER INSTITUTE

5670 Peachtree Dunwoody Road
Suite 1000
Atlanta, GA 30342

Presorted
First-Class Mail
U.S. Postage PAID
Atlanta, GA
Permit #1713