NORTHSIDE HOSPITAL CANCER INSTITUTE
BLOOD & MARROW TRANSPLANT PROGRAM

Transplant and Cellular Immunotherapy NEWS

NORTHSIDE HOSPITAL CANCER INSTITUTE
IMMUNOTHERAPY PROGRAM

FALL 2020/WINTER 2021 ISSUE

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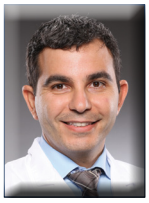

The Immunotherapy Program at Northside Hospital Cancer Institute

By: Melhem Solh, MD

The immune system, in addition to fighting infections, plays a key role in preventing cancer from occurring by identifying abnormal cells and destroying them before they develop into active malignancy. It is the ability of some of these cells to evade the immune system attack that results in patients developing cancers. Cancer immunotherapy works by boosting, re-training or engineering the patient's immune system to be more efficient at fighting cancer. Recent advances in immunotherapy provide a road map to treat and potentially cure refractory cancers, especially blood cancers and a hope that some day to be the mainstay of cancer treatment.

The Immunotherapy Program at Northside was established to provide patients in Georgia and surrounding states access to cutting-edge clinical research trials as well as commercially available immunotherapies. The mission of this Northside Cancer Institute Program is to provide exceptional care and superior survival outcomes. The program brings together expert Northside physicians in all areas of cancer sub-specialties, supported by a team of patient coordinators, nurses, midlevels, research staff, health psychologists, dietitians, physical and occupational therapists, immune cell collection and processing facility and a nationally recognized blood and marrow transplant team to provide a collaborative approach for rapid implementation of scientific advances in cancer immunotherapy.

In addition to being a certified center for the FDA-approved chimeric antigen receptor (CAR) T-cell therapies (Kymriah®, Tecartus™, and Yescarta®), the program has several ongoing immunotherapy trials ranging from conjugate antibodies, bispecific T cell engagers, CAR T-cell therapies (autologous and allogeneic), virus specific T cells, multi tumor-associated antigen T cells and natural killer (NK) cell therapies that encompass a variety of malignant and infectious etiologies including acute leukemias, multiple myeloma and lymphomas and COVID-19.

Please review our immunotherapy clinical research trials. If you have a question regarding study eligibility, please contact Stacey Brown, Northside BMT/Leukemia clinical research manager, at **404.780.7965** or stacey.brown@northside.com.

Ongoing Immunotherapy Clinical Trials

Disease	Trial Number	Name of Trial	Drug & Link to clinicaltrials.gov
Immunotherapy			
NHL	NSH1170	A Phase 1, Multicenter, Open-Label Study of JCAR017, CD19-Targeted Chimeric Antigen Receptor (CAR) T Cells, in Relapsed and Refractory (r/r) B-Cell Non-Hodgkin Lymphoma	JCAR017 NCT02631044
	NSH1226	An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	JCAR017 NCT03331198
	NSH1231	Managed Access Program (MAP) to Provide Access to CTL019, for Acute Lymphoblastic Leukemia (ALL) or Large B-cell Lymphoma Patients Without Specification Leukapheresis Product and/or Manufactured Tisagenlecleucel Out of Specification for Commercial Release	CTL019 NCT03601442

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Ongoing Immunotherapy Clinical Trials *(continued from page 1)*

Disease	Trial Number	Name of Trial	Drug & Link to clinicaltrials.gov
Immunotherapy			
NHL	NSH 1251	A Phase 1, Multicenter, Open-Label Study of CC-97540, C19-Targeted NEX-T Chimeric Antigen Receptor (CAR) T Cells, in Subjects with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma	CC-97540 NCT04231747
	NSH1259	A Phase 2, Open-Label , Single-Arm Study to Evaluate the Efficacy and Safety of Camidaniumab Tesirine (ADCT-301) in Patients with Relapsed or Refractory Hodgkin Lymphoma	ADCT-301 NCT04052997
	NSH1261	A Phase 1 Multidose Study to Evaluate the Safety and Tolerability of XMAB13676 in Patients with CD20-Expressing Hematologic Malignancies	XMAB13676 NCT02924402
	NSH1270	A Phase 1/2a, Open-Label, Dose-escalation, Dose-expansion, Parallel Assignment Study to Evaluate the Safety and Clinical Activity of PBCAR0191 in Subjects with Relapsed/Refractory (r/r) Non-Hodgkin Lymphoma (NHL) and r/r B-cell Acute Lymphoblastic Leukemia (B-ALL)	PBCAR0191 NCT03666000
	NSH1282 (Open Jan 2021)	Expanded Access Protocol (EAP) for Patients Receiving Lisocabtagene Maraleucel that is Nonconforming for Commercial Release	Lisocabtagene Maraleucel NCT04400591
	NSH1297 (Open Jan 2021)	A Phase 1/ 2 Open-Label Study to Evaluate the Safety and Efficacy of Loncastuximab Tesirine and Ibrutinib in Patients with Advanced Diffuse Large B-Cell Lymphoma or Mantle Cell Lymphoma	Loncastuximab Tesirine and Ibrutinib NCT03684694
Multiple Myeloma	NSH1216	A Phase 3, Multicenter, Randomized, Open-Label Study to Compare the Efficacy and Safety of bb2121 Versus Standard Triplet Regimens in Subjects with Relapsed and Refractory Multiple Myeloma (rrMM) (KarMMa-3)	bb2121 NCT03651128
	NSH1224	A Phase I, Open Label Study to Evaluate the Safety, Pharmacokinetic, Pharmacodynamic and Clinical Activity of PF-06863135, A B-Cell Maturation Antigen (BCMA) – CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Advanced Multiple Myeloma (MM)	PF-06863135 NCT03269136
	NSH1277 (Open Jan 2021)	A Phase 1, Open-Label, Multicenter Study to Evaluate the Safety of bb2121 in Subjects with High-Risk Newly Diagnosed Multiple Myeloma (KarMMa-4)	bb2121 NCT04196491
	NSH1298 (Open March 2021)	Expanded Access Protocol (EAP) for Subjects Receiving Idecabtagene Vicleucel That Is Non-Conforming for Commercial Release bb2121-EAP-001	bb2121-EAP-001
AML/MDS	NSH1296 (Open April 2021)	Phase 1 Study of Escalating Single and Multiple Doses of Mana 312 (Multi Tumor-Associated Antigen T Cells) Administered to Adult Subjects with AML or MDS after Allogeneic Hematopoietic Stem Cell Transplant	Mana
	C394 (Open Dec 2020)	BMT CTN 1803 Haplo-Identical Natural Killer (NK) Cells to Prevent Post-Transplant Relapse in AML and MDS	NCT04395092
ALL	NSH1231	Managed Access Program (MAP) to Provide Access to CTL019, for Acute Lymphoblastic Leukemia (ALL) or Large B-cell Lymphoma Patients Without Specification Leukapheresis Product and/or KManufactured Tisagenlecleucel Out of Specification for Commercial Release	CTL019 NCT03601442
	NSH1270	A Phase 1/2a, Open-Label, Dose-escalation, Dose-expansion, Parallel Assignment Study to Evaluate the Safety and Clinical Activity of PBCAR0191 in Subjects with Relapsed/Refractory (r/r) Non-Hodgkin Lymphoma (NHL) and r/r B-cell Acute Lymphoblastic Leukemia (B-ALL)	PBCAR0191 NCT03666000
SLL/CLL	NSH1226	An Open-Label, Phase 1 Safety and Phase 2 Randomized Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	JCAR017 NCT03331198
Hematological Malignancies	NSH1164	A Phase 1 Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb® 14045 in Patients With CD123-Expressing Hematologic Malignancies	XmAB® 14045 NCT02730312
Hemorrhagic Cystitis	C429 (Open March 2021)	A Phase 3 Multicenter, Double-Blind, Placebo-Controlled Trial of Viralym-M (ALVR105) for the Treatment of Patients with Virus-Associated Hemorrhagic Cystitis after Allogeneic Hematopoietic Cell Transplant	ALVR105 NCT04390113
Respiratory Viruses	C434 (Open Spring 2021)	Phase 1/2, Double-Blind, Placebo-Controlled, Dose Escalation and Expansion Study of ALVR106 for the Treatment of High-Risk Patients with Respiratory Viral Infections after Hematopoietic Cell Transplant	ALVR105

Dr. Scott Solomon Co-Authors Novel Clinical Research CAR T-Cell Peer Reviewed Article

The Immunotherapy Program at Northside Hospital participated in a pivotal clinical research trial entitled, "A global randomized, multicenter phase 3 trial to compare the efficacy and safety of JCAR017 to standard of care in adult subjects with high-risk, transplant-eligible relapsed or refractory aggressive B-cell Non-Hodgkin Lymphomas (TRANSFORM)." Study results were recently published in the peer-reviewed medical journal Lancet.

Major highlights of the study were:

- Complete response (CR): 53%, 65% of which maintained past one year
- Cytokine release syndrome (CRS): median five days, grade 3/4 in 2%
- Immune effector cell-associated neurotoxicity syndrome (ICANS): median nine days, grade 3/4 in 9%
- Prolonged grade 3/4 cytopenias past day 29 in 37%

We thank all of our patients and staff members who participated in this important clinical research trial.

The Northside Hospital BMT Difference

- Only attending BMT physicians take calls after hours and on weekends.
- All BMT physicians focus on clinical patient care year-round.
- Outpatient based allogeneic transplant program has been shown to improve survival outcomes.
- Dedicated specialty designed 56-bed inpatient HEPA filtered unit
- High ratio of BMT trained pharmacists-to-patients
- Outstanding re-accreditation with the Foundation of Accreditation for Cellular Therapy (FACT) with no clinical deficiencies for the last six consecutive tri-annual inspections

CAR T-Cell Outpatient Infusion Is Now Available

Chimeric antigen receptor (CAR) T-cell therapies are at the forefront of adoptive cell transfer therapies, in which patients' own immune cells are utilized to treat their cancer. With autologous CAR T-cell therapy, the patient's blood is collected, and T cells are then genetically modified and reinfused into the patient. The use of adoptive cell therapy after administration of an immunodepleting preparative regimen has been shown to provide curative potential for otherwise refractory blood malignancies.

CAR T-cell therapies are currently administered at a limited number of Foundation for the Accreditation of Cellular Therapy (FACT) accredited cancer centers, are primarily delivered in an inpatient setting and require a post-infusion admission for several days. Patients may experience an exaggerated immune response known as cytokine release syndrome (CRS), which could result in significant morbidity and mortality if not diagnosed and treated promptly. However, ongoing clinical experience has provided the safety and feasibility of administering CAR T-cell therapy as an outpatient process in clinical practices. Not all CAR T-cell products are the same and therefore have varying toxicity profiles. A true assessment of the appropriate setting for the administration of a patient's cellular therapy is dependent upon the CAR T-cell product utilized, patient disease status, availability of caregivers to ensure specific safety requirements for the safe administration and monitoring of the patient and the experience of the center providing treatment.

The Immunotherapy Program at Northside Hospital is currently offering several CAR T-cell therapy outpatient infusions, where the patient is followed on a daily basis in the outpatient clinic. This transition mirrors our current autologous and allogeneic hematopoietic stem cell transplant therapy program. The patient must be an approved candidate for outpatient therapy with an available caregiver to provide daily outpatient visits as well as live close to the treatment center in the event he or she needs to be quickly admitted if signs of CRS or neurotoxicity symptoms develop.

Post-infusion, close monitoring of the patient is required to assess for any complications. CAR T-cell therapies are not all the same and may have varying degrees of side effects and toxicities. Patients and family/caregivers must fully understand the specific side effect profile for the CAR T-cell product administered. Caregivers

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CAR T-Cell Outpatient Infusion Is Now Available *(continued from page 3)*

should receive education to assess for changes in cognition and other potential neurological toxicities. The seriousness of any toxicity should be reported early and evaluated immediately, as the intensity of the toxicity can escalate quickly in some cases. Close care coordination with the patient, family/caregivers and health care team is absolutely essential. Patients who receive CAR T-cell therapy with intent for outpatient follow-up will have 24/7 access to one of the BMT physicians specializing in the specific therapeutic disease area and trained in the management of patients receiving cellular therapies, who can diagnose and begin early management of any complications. If a patient develops serious side effects, hospital admission will be required. The potential for a hospital admission will be planned, so the patient can be fast-tracked to a designated bed.

For select hematologic malignancies, CAR T-cell therapy has succeeded where conventional therapies have failed. The Immunotherapy Program at Northside continues to offer hope to patients who have exhausted all other treatment options, ushering in a new era of cancer treatment.

More CAR T-Cell Therapies Available at the Immunotherapy Program at Northside Hospital

We are pleased to announce additional treatment options are now available at the Immunotherpy Program at Northside Hospital. TECARTUS™ (brexucabtagene autoleucel), the first and only FDA-approved CD19-directed genetically modified autologous T cell immunotherapy (CAR T-cell), is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). This indication was approved under accelerated approval based on overall response rate and durability of response.[1,2]

Northside is also an FDA-approved CAR T-cell center offering several additional products as shown in the table on the next page. Please call **404.255.1930** to speak with a physician or to refer a patient.

KYMRIAH® (tisagenlecleucel) Suspension for IV infusion

KYMRIAH® is a CD19-directed genetically modified autologous T cell immunotherapy to treat adult patients with two types of blood-derived cancers: patients up to the age of 25 with a diagnosis of B-cell acute lymphoblastic leukemia (ALL) that is refractory or in a second or greater relapse and adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.[3]

TECARTUS™ (brexucabtagene autoleucel) Suspension for IV infusion
NOW APPROVED WITH FDA BREAKTHROUGH THERAPY DESIGNATION†

TECARTUS™ (brexucabtagene autoleucel), a CD19-directed genetically modified autologous T cell immunotherapy (CAR T-cell), is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.[1,2]

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

YESCARTA®, axicabtagene ciloleucel, is a CD19-directed genetically modified autologous T cell immunotherapy and first FDA-approved CAR T-cell therapy for adult patients with certain types of non-Hodgkin lymphoma (NHL) who have relapsed or refractory disease after receiving two or more types of treatment.[4]

References:

1. BusinessWire.com Press Release. Kite submits biologics license application to U.S. Food and Drug Administration for company's second CAR T cell therapy. https://www.businesswire.com/news/home/20191211005861/en/. Published December 11, 2019. Accessed June 15, 2020.
2. TECARTUS™. Package insert. Kite Pharma, Inc; 2020.
3. KYMRIAH®. Package insert. Novartis Pharmaceuticals Corporation; 2018.
4. YESCARTA®. Package insert. Kite Pharma, Inc; 2020.

Northside Hospital BMT Ranks Among National Leaders in Allogeneic Transplantation

For the eleventh consecutive year (2009-19), Northside BMT achieved survival outcomes that significantly exceeded the expected range as reported in the Center for International Blood and Marrow Transplant Research (CIBMTR) Final 2019 Transplant Center Specific Survival Report, December 16, 2019 and from reported outcome data from Be The Match®.

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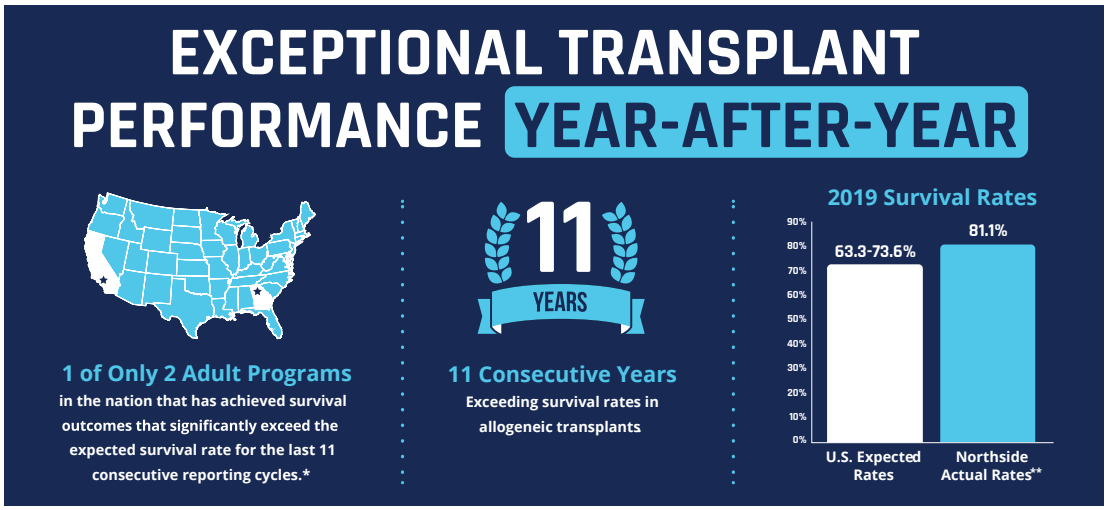
Northside Hospital BMT Ranks Among National Leaders in Allogeneic Transplantation *(continued from page 4)*

One hundred seventy adult and pediatric transplant centers were included in the analysis of patients who received their first allogeneic transplant between January 1, 2015 and December 31, 2017 using unrelated or related donors and who had reported follow-up. ***The one-year survival of patients transplanted at Northside Hospital was 81.1%.****

Northside BMT is one of only two adult BMT programs in the U.S. that achieved survival outcomes that significantly exceeded their expected survival rate for the last 11 consecutive reporting cycles, and Northside BMT is the only program in Georgia to overperform.

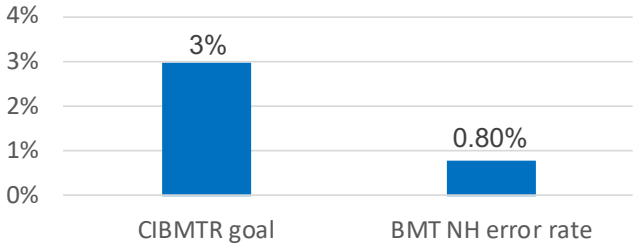
"The BMT Program at Northside is the largest allogeneic transplant program in Georgia," said H. Kent Holland, MD, medical director of the BMT Program at Northside Hospital Cancer Institute. "Our success is a direct reflection of the combined experience and expertise of the teams in our inpatient and outpatient BMT units, our stem-cell laboratory and blood donor center."

Innovative treatments and research are major components of the BMT Program at Northside, which includes chimeric antigen receptor (CAR) T-cell therapy and other immunotherapy treatment options as well as novel clinical research trials.



Congratulations to Our Data Management Team for Continuously Providing Outstanding Data to CIBMTR and BMT CTN

In 2020, our program underwent two external quality data audits: CIBMTR (Center for International Blood and Marrow Transplant Research) and BMT CTN (Blood and Marrow Transplant Clinical Trial Network). Both audits resulted in error rates lower than the national standard.



External Quality Reports: CIBMTR Data Audit

NORTHSIDE HOSPITAL
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CIBMTR: Center for International Bone Marrow Transplant Research

- **All US transplant programs are required to submit data for autologous, allogeneic and other cell therapy**
- **Centers are audited every 4 years for critical data fields**
- **Program audited March 2-5, 2020 over 7000 critical data fields with a 0.8% error rate**
- **5th consecutive data quality audit by CIBMTR with a critical field error rate of less than 3%.**

RESEARCH UPDATES

NORTHSIDE HOSPITAL
BUILT TO BEAT CANCER

Blood and Marrow Transplant Clinical Trial Network (BMTCTN) CORE CENTER

Awarded in 2011 from National Cancer Institute (NCI)	Re-selected in 2017 as the lead site of a consortium through a competitive grant process	1 of 20 centers in nation and the only lead consortium site in GA
BMTCTN Goals Scientific/Administrative Accrual Activation and Enrollment Data and Lab Compliance	2019 Center Performance Report Rating = 98% "Outstanding"	Highlights Dr. Bashey: Donor Selection Committee Dr. Solh: BMTCTN 1703 Protocol Team

Dr. Melhem Solh Presented Current Updates in Myelodysplastic Syndromes (MDS) at the 2020 Virtual Blood Cancer Georgia Conference

2020 Castle Connolly Top Doctor Awards

We are proud to announce our five BMTGA physicians were selected as 2020 Castle Connolly Top Doctor recipients and were recently featured in the New York Times. We congratulate our dedicated physicians.

2019 Northside Hospital BMT Program Survivor Reunion Draws Over 600 Participants

On October 12, 2019, over 600 survivors, caregivers, physicians and staff attended the 2019 Northside BMT Survivor Reunion held at Mercedes Benz Stadium. Survivors from one year post-transplant to 22 years post-transplant attended the reunion. We thank everyone who made the reunion a success.

BMT/Leukemia Protocols

Disease	Trial Number	Name of Trial	Drug & Link to clinicaltrials.gov
Leukemia, BMT and Supportive Care			
AML	NSH1169	A Phase I/II Study of SEL24 in Patients with Acute Myeloid Leukemia	SEL124 NCT03008187
	NSH1208	A Phase 1 Trial to Evaluate the Potential Impact of Renal Impairment on the Pharmacokinetics and Safety of CPX-351 (Daunorubicin and Cytarabine) Liposome for Injection Treatment in Adult Patients with Hematologic Malignancies	Vyxeos NCT03555955
	NSH1238	A Phase Ib Study of SEL120 in Patients with Acute Myeloid Leukemia and High-Risk Myelodysplastic Syndrome	SEL120 NCT04021368
	NSH1260	A Phase I, Parallel, Open-Label Study of the Safety and Tolerability, Pharmacokinetics, and Antileukemic Activity of ASTX660 as a Single Agent and in Combination with ASTX727 in Subjects with Acute Myeloid Leukemia	ASTX727 NCT04155580
	C374	A Phase III Randomized, Double-Blind Trial to Evaluate the Efficacy of Uproleselan Administered with Chemotherapy Versus Chemotherapy Alone in Patients with r/r AML	Uproleselan(GMI-1271) NCT03616470
Transplant			
	NSH1246	Phase II Trial Evaluating the Efficacy and Safety or Sargramostim Post Infusion of T-Replete HLA Mismatched Peripheral Blood Haploidentical Stem Cells with Post Transplant Cyclophosphamide	Sargamostim NCT04237623
AML	NSH1150	Phase 2 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	Pembrolizumab NCT02771197
Aplastic Anemia	NSH1158	A Study of T Cell Replete, HLA-Mismatched Bone Marrow Transplantation with Post-Transplant Cyclophosphamide as a Front-Line Therapy for Patients with Severe Aplastic Anemia Lacking HLA-Matched Related Donor	Fludarabine Cyclophos NCT02828592
Allogeneic Donors	NSH1166	Infusion of CD34+ Selected Donor Hematopoietic Stem Cells/Bone Marrow Using the CliniMACS Humanitarian Use Device Protocol	NONE
Post Transplant			
GVHD	NSH1219	Phase II Trial Evaluating the Safety and Efficacy of Combined CD20- and BTK-Targeted B Cell Depleting Therapy with Rituximab and Ibrutinib in the Primary Treatment of Chronic Graft-Versus Host Disease	Rituximab and Ibrutinib NCT04235036
	C369	BMT CTN 1703 A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate Versus Post-Transplant Cyclophosphamide/ Tacrolimus/ Mycophenolate Mofetil in Non-Myeloablative/ Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation	NCT03959241
	C401	BMT CTN 1705 – A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase III Trial of Alpha1-Antitrypsin (AAT) Combined with Corticosteroids Versus Corticosteroids Alone for the Treatment of High Risk Acute Graft-Versus-Host Disease (GVHD) Following Allogeneic Hematopoietic Stem Cell Transplant	Alpha1-Antitrypsin (AAT) NCT04167514
Multiple Myeloma	C389	Phase III Study of Daratumumab/rHuPh20 (NSC-810307) Plus Lenalidomide or Lenalidomide as Post Autologous Stem Cell Transplant Maintenance Therapy in Patient with Multiple Myeloma (MM) using Minimal Residual Disease to Direct Therapy Duration (Dramatic Study).	Daratumumab/ rHuPh20 (NSC-810307) NCT04071457
NHL	C282	Alliance A)51301-A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype.	NCT02443077
Supportive Care/Other			
	NSH721	NMDP Recipient Consent for Participation in Registry, Research Database, and Research Sample Repository	NCT00495300 (sample) NCT01166009 (database)
	NSH943	A Multicenter Access and Distribution Protocol for Unlicensed Cryopreserved Cord Blood Units (CBUs) for Transplantation in Pediatric and Adult Patients with Hematologic Malignancies and Other Indications	NCT01351545
	NSH995	A Multicenter Safety Study of Unlicensed, Investigational Cryopreserved Cord Blood Units (CBUs) Manufactured by the National Cord Blood Program (NCBP) and Provided for Unrelated Hematopoietic Stem Cell Transplantation of Pediatric and Adult Patients	NCT01656603
	C373	BMT CTN 1702 Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation	NCT03904134
	C393	BMT CTN 1704 Composite Health Assessment Model for Older Adults: Applying Pre-Transplant Comorbidity, Geriatric Assessment, and Biomarkers to Predict Non-Relapse Mortality after Allogeneic Transplantation (CHARM)	NCT03992352

Blood & Marrow Transplant Group
at Northside Hospital
5670 Peachtree Dunwoody Road
Suite 1000
Atlanta, GA 30342

BMTGA Physicians

(L-R) Drs. H. Kent Holland, Asad Bashey, Melhem Solh, Scott Solomon and Lawrence Morris

Effective January 1, 2021
BMTGA/Northside Hospital is an in-network Ambetter™ provider.

To make a referral, or to speak with a physician, please call 404.255.1930.

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