BMT News

Northside Hospital Cancer Institute
Blood & Marrow Transplant Program

WINTER 2018 ISSUE

BMT Program at Northside Renews its Status as a Core Clinical Center for the Blood and Marrow Transplant Clinical Trials Network

Blood and Marrow Transplant Clinical Trials Network

Northside Hospital Cancer Institute's Blood and Marrow Transplant (BMT) Program is pleased and honored to learn that it is one of twenty BMT Programs and Program Consortia to be selected as a **Core Clinical Center** for the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). This award is for the new project period, which runs from 2017 through 2024. Successful centers were selected following a highly competitive application process, which was open to all BMT programs in the United States. The selection process, which was run by the National Heart Lung and Blood Institute (NHLBI), involved an assessment of each applicant center's program size, commitment to clinical research, and innovative approach to blood and marrow transplantation. Applicant centers also had to submit a novel clinical trial proposal designed to address an important need in the field of BMT. The entire application, including the clinical trial proposal, was evaluated by a team of national and international clinical researchers in BMT brought together by the NHLBI. The lead centers selected as the 20 Core Clinical Centers for this new project period are as follows:

1) Baylor College of Medicine, Houston, TX
2) City of Hope Medical Center, Duarte, CA
3) Children's Hospital, Los Angeles, CA
4) Dana-Farber Cancer Institute, Boston, MA
5) Duke University, Durham, NC
6) Fred Hutchinson Cancer Research Center, Seattle, WA
7) H. Lee Moffitt Cancer Center, Tampa, FL
8) Mount Sinai School of Medicine, New York, NY
9) Johns Hopkins University, Baltimore, MD
10) Medical College of Wisconsin, Milwaukee, WI
11) **Northside Hospital, Atlanta, GA**
12) The Ohio State University, Columbus, OH
13) Oregon Health and Science University, Portland, OR
14) Stanford University, Stanford, CA
15) Memorial Sloan Kettering Cancer Center, New York, NY
16) University of Florida, Gainesville, FL
17) University of Michigan, Ann Arbor, MI
18) University of Minnesota, Minneapolis, MN
19) University of Pennsylvania, Philadelphia, PA
20) Washington University, St. Louis, MO

The BMT CTN is the only federally-funded national cooperative clinical trials network charged with conducting multicenter phase III and innovative phase II trials in the field of hematopoietic cell transplantation and other forms of cellular therapy. It is jointly administered by the NHLBI and the National Cancer Institute (NCI). Established in October 2001, the BMT CTN has since held two renewal/reapplication cycles (2011 and 2017), in which programs compete for Core Clinical Center designation. The BMT Program at Northside was selected as a Core Clinical Center following its first application in 2011. Its re-selection in 2017 is a testament to its contribution to the BMT CTN during the last cycle. Additionally, its innovative investigator-initiated research program, particularly in the rapidly expanding field of HLA-haploidentical donor transplantation, is considered an international center of expertise. Two other BMT programs, the University of Miami, in Miami, FL, and the Levine Cancer Center/Carolinas Healthcare

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BMT Program at Northside Renews its Status as a Core Clinical Center for the Blood and Marrow Transplant Clinical Trials Network *(continued from page 1)*

System, in Charlotte, NC, joined Northside as consortium centers for this application period. We look forward to scientific and clinical collaboration with these centers.

This funding period for the BMT CTN brings with it an additional interest in BMT clinical trials for non-malignant hematology. In this regard, the BMT Program at Northside has already activated two innovative trials that investigate the use of HLA-haploidentical donors for sickle cell disease (BMT CTN 1507) and for severe aplastic anemia (BMT CTN 1502). These studies are particularly relevant in metropolitan Atlanta and the State of Georgia because these geographic areas contain large African-American populations. Despite the recognition that allogeneic hematopoietic cell transplantation remains the only curative treatment for these non-neoplastic but life-threatening diseases, most patients will not have a matched sibling donor. Furthermore, the probability of finding an optimally-matched, volunteer, unrelated donor is typically less than 20% for African-American patients. The use of HLA-haploidentical donors provides almost universal donor access to these patients. Furthermore, the documented lower incidence of chronic graft versus host disease following haploidentical donor transplantation (compared to matched unrelated donor transplantation) may dramatically improve quality of life. This is because the potential benefit of chronic graft-versus-host disease (GVHD) in reducing relapse is not relevant for patients with these non-neoplastic conditions. Both BMT CTN 1507 and 1502 utilize innovative treatment regimens to maximize donor engraftment and minimize the risk of GVHD.

Open BMT CTN Clinical Trials, Including **Two Innovative Trials for Non-Malignant Hematology**

NSH1156: BMT CTN 1501 – A Randomized, Phase II, Multicenter, Open Label, Study Evaluating Sirolimus and Prednisone in Patients with Refined Minnesota Standard Risk, Ann Arbor 1/2 Confirmed Acute Graft vs Host Disease

STUDY OBJECTIVES

Primary:

Assess the rate of CR/PR on day 28 post randomization in patients with standard-risk acute GVHD defined by both clinical and refined Minnesota Standard Risk and Ann Arbor (AA) 1/2 risk status.

ELIGIBILITY CRITERIA

Inclusion Criteria:

- Standard-risk acute GVHD according to refined Minnesota Criteria after allogeneic hematopoietic cell transplantation. Requires meeting one of the criteria in the table below:

Single organ involvement	Multiple organ involvement
i. Stage 1-3 skin	i. Stage 1-3 skin plus stage 1 upper GI
ii. Stage 1 upper GI	ii. Stage 1-3 skin plus stage 1 lower GI
iii. Stage 2 lower GI	iii. Stage 1-3 skin plus stage 1 lower GI plus stage 1 upper GI
	iv. Stage 1-3 skin plus stage 1-4 liver
	v. Stage 1 lower GI plus stage 1 upper GI

Exclusion Criteria:

- May not be receiving Sirolimus for any indication within 14 days of screening for enrollment
- Patients must not be receiving systemic immune suppressive therapy for treatment of active GVHD (topical skin and GI corticosteroids are allowed)

NSH1175: BMT CTN 1502 – Optimizing Cord Blood and Haploidentical Aplastic Anemia Transplantation (CHAMP)

STUDY OBJECTIVES

Primary:

Assess overall survival separately in two cohorts (UCB and haplo) at one year post-HSCT in patients with SAA

ELIGIBILITY CRITERIA

Inclusion Criteria:

- Failed at least one trial of immunosuppressive therapy

Exclusion Criteria:

- Inherited bone marrow failure syndromes
- Presence of anti-donor HLA antibodies
- Alemtuzumab or ATG within 2 weeks of enrollment

NSH1182: BMT CTN 1506 – A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of the FLT3 Inhibitor Gilteritinib Administered as Maintenance Therapy Following Allogeneic Transplant for Patients with FLT3/ITD AML

STUDY OBJECTIVES

Primary:

Compare RFS between participants with FLT3/ITD AML in CR1 who undergo transplant and are randomized to receive gilteritinib or placebo beginning after time of engraftment for a two-year period

ELIGIBILITY CRITERIA

Inclusion Criteria:

- Confirmed AML in CR1
- Not received more than 2 cycles of induction
- Presence of FLT3/ITD mutation at diagnosis

Exclusion Criteria:

- Prior allo transplant
- QTcF >450 msec
- Requires treatment with strong inducers of CYP3A4

NSH1184: BMT CTN 1507 – Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients with Symptomatic Sickle Cell Disease

STUDY OBJECTIVES

Primary:

Estimate event-free survival (EFS) at 2 years after a reduced intensity conditioning regimen and haplo transplant in adults with severe SCD

ELIGIBILITY CRITERIA

Inclusion Criteria:

- Age 15-45
- SCD and have one or more:
  - Stroke or neurological deficit >24 hrs
  - History of ≥2 episodes of acute chest syndrome in 2 years prior to study
  - History of ≥3 severe vaso-occlusive pain crises per year in 2 years prior to study
  - Administration of regular RBC transfusion (≥8 per year for ≥1 year)
  - TRJV ≥2.7 m/sec

Exclusion Criteria:

- Prior allo transplant
- Anti-donor specific HLA antibodies

BE THE MATCH®

Updated Referral Guidelines: Recommended Timing for Transplant Consultation

Disease stage at the time of transplant can have a significant impact on patient survival[1]. Appropriate planning and early donor identification are critical for optimal outcomes.

The updated 2017 referral timing guidelines were developed jointly by the National Marrow Donor Program® (NMDP)/Be The Match® and the American Society for Blood and Marrow Transplantation (ASBMT) and are based on current clinical practice, medical literature, and evidence-based reviews[1,2].

The guidelines highlight disease categories that include patients at risk for disease progression, who should be referred for consultation for autologous or allogeneic HCT[3].

For more information, please visit **https://bethematchclinical.org/transplant-indications-and-outcomes/referral-timing-guidelines/**

If you have questions as to when to refer a patient for initial transplant consult, please call **404-255-1930** and ask to speak to one of our transplant physicians.

1. Lee, SJ, Klein J, Haagenson M, et al. High-resolution donor-recipient HLA matching contributes to the success of unrelated donor marrow transplantation. *Blood.* 2007;110(13): 4576-4583. Access
2. Pidala J, Lee SJ, Ahn KW, et al. Nonpermissive HLA-DPB1 mismatch increases mortality after myeloablative unrelated allogeneic hematopoietic cell transplantation. *Blood.* 2014:124(16):2596-2606. Access
3. NMDP/Be The Match & ASBMT Recommended Timing for Transplant Consultation, 2017.

New Transplant Guideline Mobile App is Now Available

To help physicians with the reference materials they need to care for transplant patients, Be The Match® has developed a free Transplant Guideline mobile app, available through the Apple© and Android™ app stores.

For more information please visit **https://bethematch.org/about-us/how-we-help-patients/transplant-education/**

Community Engagement

Myeloproliferative Neoplasm Patient Education Event

Maria Hanik, DNP, APRN-BC, OCN, BMTC

Patients with Myeloproliferative Neoplasms (MPN) joined local and national medical experts on October 26, 2017 at a MPN Advocacy & Education International meeting. The meeting was held at the Georgia Terrace and focused on the many factors in diagnosing, treating and living with bone marrow-related neoplasms. A BMT/Leukemia Program Advanced Practice Provider, Maria Hanik, DNP, APRN-BC, OCN, BMTC, presented on the role of stem cell transplant in myelofibrosis, reviewed the types of patients who would benefit most from this treatment, and how to choose a transplant center with excellent quality and survival outcomes.

We would like to thank our patient Marina Peed, whose commitment to MPN Advocacy and Education International helped bring this national patient education meeting to Atlanta.

BMT/Leukemia Team Participates in the 2017 Light The Night Fundraising Walk

For the first time in nineteen years, the **Leukemia and Lymphoma Society's (LLS)** Light The Night Walk was held at Piedmont Park, in Atlanta. On October 7, 2017, survivors, patients, families, and practitioners gathered together to celebrate, honor and remember those touched by cancer. The walk itself is a showing of emotional support for our patients during their cancer journey. The proceeds from this fundraising event also provide our patients with financial support.

The BMT/Leukemia team was led by the inpatient staff. This year, Northside Hospital Cancer Institute (NHCI) sponsored a survivor tent, where survivors had the opportunity to obtain a swag bag, enjoy refreshments, and take a photo. Other NHCI activities included a remembrance dome, a tailgate zone, a team photo booth, selfie stations, and a kids' zone.

Over 12,000 survivors, family members, caregivers, and friends participated, making the Atlanta Light The Night event the number one walk in the country. Over 1.2 million dollars were raised, ranking the walk tenth in the USA for fundraising dollars. We thank all those who participated and supported the 2017 LLS Light The Night Walk.

Regional and National News

BMT/Leukemia Program Presents Groundbreaking Study at the 2017 American Society of Hematology (ASH) Conference

Dr. Scott Solomon presented a groundbreaking study: "Selecting the Best Donor for T-Cell-Replete Haploidentical Transplantation: Importance of HLA Disparity, NK Alloreactivity, and Other Clinical Variables", at the 2017 ASH conference, held in Atlanta, Georgia. The study identified new donor selection criteria, including HLA DP typing and KIR genotyping, tests which are not currently being performed routinely for donor selection. These criteria are important factors in selecting the best haploidentical donor. The study also showed that when these two criteria were met, patient survival rates increased.

This study would not have occurred without the generous support of the Northside Hospital Foundation's Cancer Research Fund. Through donations, this fund provides Northside Hospital Cancer Institute investigators the ability to develop cutting-edge research for cancer treatment, prevention, early detection, survivorship, and more.

BMT-GA Physicians

BMT/Leukemia Program Clinical Research Team

Dr. Scott Solomon Presents at the 2017 Multiple Myeloma Rounds Atlanta Program

Dr. Scott Solomon also presented "Multiple Myeloma: First Relapse and Beyond" at the 2017 Multiple Myeloma Rounds Atlanta Program, joining Atlanta hematology-oncology physicians from the academic and community settings. The meeting reviewed the most current multiple myeloma treatment modalities for patients in various stages of disease.

Attendees included referring physicians, mid-level providers, and other allied healthcare providers. PleXus Communications in collaboration with Rush University, Leukemia Research Foundation, and the Amyloidosis Foundation sponsored this CME/CE-accredited educational dinner program.

Open Clinical Trials

Disease	Trial Number	Name of Trial	Drug & Link to www.clinicaltrials.gov
AML	NSH1144	A Phase 2, Randomized, Biomarker-Driven, Clinical Study in Patients With Relapsed/Refractory AML With an Exploratory Arm in Patients With Newly Diagnosed High-Risk AML	Alvocidib NCT02520011
	NSH1164	A Phase I Multiple Dose Study to Evaluate the Safety and Tolerability of XmAb® 14045 in Patients With CD123-Expressing Hematologic Malignancies	XmAB® 14045 NCT02730312
	NSH1169	A Phase I/II Study of SEL24 in Patients with Acute Myeloid Leukemia	SEL24 Selvita NCT03008187
	C250	A Phase 1, Open-Label, Dose-escalation, Multicenter Study to Evaluate the Tolerability, Safety, Pharmacokinetics, and Activity of ADCT-301 in Patients With Relapsed or Refractory CD25-Positive Acute Myeloid Leukemia (AML)	ADCT-301 NCT02588092
	C262	A Phase 3 Open-Label, Multicenter, Randomized Study of ASP2215 Versus Salvage Chemotherapy in Patients With Relapsed or Refractory AML With FLT3 Mutation	ASP2215 NCT02421939
ALL	NSH1099	E1910: Phase 3 Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL Negative B-ALL in Adults	Blinatumomab NCT02003222
B-Cell Malignancies	NSH1165	Phase 1, Dose-Escalation Study to Evaluate the Tolerability, Safety, Pharmacokinetics, and Antitumor Activity of ADCT-402 in Patients With Relapsed or Refractory B-Cell Lineage Non Hodgkin Lymphoma (B-NHL)	ADCT-402 NCT02669017
	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

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Open Clinical Trials

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Disease	Trial Number	Name of Trial	Drug & Link to www.clinicaltrials.gov
Transplant	NSH1074	A Phase II Trial of Nonmyeloablative Haploidentical Peripheral Blood Stem Cell Transplantation Followed by Maintenance Therapy with the Novel Oral Proteasome Inhibitor, MLN9708, in Patients With High-Risk Hematologic Malignancies.	MLN9708 NCT02169791
	NSH1107	A Phase II Trial of High-Dose Bendamustine, Etoposide, Cytarabine, and Melphalan (BeEAM) in the Upfront Treatment of Multiple Myeloma	Bendamustine NCT02416206
	NSH1108	BMT CTN 1301 – A Randomized, Multicenter Phase III Trial of Calcineurin Inhibitor-Free Interventions for Prevention of Graft Versus Host-Disease	NCT02345850
	NSH1125	A Multicenter Phase II, Double-Blind Placebo Controlled Trial of Maintenance Ixazomib After Allogeneic Hematopoietic Stem Cell Transplantation for High-Risk Multiple Myeloma BMT CTN 1302	Ixazomib NCT02440464
	NSH1132	A Phase II Trial of Reduced Intensity Conditioning and Transplantation of Partially HLA-Mismatched Peripheral Blood Stem Cells for Patients With Hematologic Malignancies	Fludarabine Melphalan Cytoxan NCT02581007
	NSH1150	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	Pembrolizumab NCT02771197
	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
	NSH1172	A Phase II Study Evaluating the Safety and Efficacy of BL-8040 for the Mobilization of Donor Hematopoietic Stem Cells and Allogeneic Transplantation in Patients With Advanced Hematological Malignancies	BL-8040 NCT02639559
	NSH1175	BMT CTN 1502 – Optimizing Cord Blood and Haploidentical Aplastic Anemia Transplantation (CHAMP)	Antithymocyte Globulin Fludarabine Cyclophos NCT02918292
	NSH1184	Reduced Intensity Conditioning for Haploidentical Bone Marrow Transplantation in Patients With Symptomatic Sickle Cell Disease	NCT03263559
	C282	Alliance A051301 – 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	Ibrutinib NCT02443077
Post Transplant	NSH1032	A Phase I/Ib Study of Ipilimumab or Nivolumab in Patients With Relapsed Hematologic Malignancies After Allogenic Hematopoietic Cell Transplantation	Ipilimumab or Nivolumab NCT01822509
	NSH1156	BMT CTN 1501 – A Randomized, Phase 2, Multicenter, Open-Label Study Comparing Sirolimus to Prednisone in Patients With Minnesota Standard Risk, Ann Arbor 1/2 Confirmed Acute GVHD	NCT02806947
	NSH1173	A Phase 1 Study of Donor BPX-501 T Cell Infusion for Adults With Recurrent or Minimal Residual Disease Hematopoietic Malignancies Post-Allogenic Transplant	Donor BPX-501 NCT02477878
	NSH1182	BMT CTN 1506 Randomized Trial of FLT3 Inhibitor vs Placebo as Maintenance Therapy Post Allogeneic Transplant	Gilteritinib NCT02997202
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

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