

Physicians at BMTGA:

H. Kent Holland, M.D.  
FACT Program Director

Lawrence E. Morris, Jr., M.D.  
Director of Leukemia  
Services

Scott R. Solomon, M.D.  
Medical Director, Stem  
Cell Processing Lab

Asad Bashey, M.D., Ph. D.  
Director of Clinical

#### IN THIS ISSUE:

Northside Hospital  
Awarded Prestigious  
NCCCP Status by National  
Cancer Institute (NCI)

NSH BMT Group  
Open Protocols

Be The Match Foundation®  
Teams up with  
The Blood and Marrow  
Transplant Program at  
Northside Hospital

Northside Hospital's  
Hematopoietic Stem Cell  
Processing and Flow  
Cytometry/Molecular  
Diagnostic Laboratories

Randomized Trial of  
SGN-35 Antibody  
Post-Autologous  
Transplant at  
Northside Hospital

# The Blood and Marrow Transplant Program at Northside Hospital

# News

SUMMER 2010

[www.bmtga.com](http://www.bmtga.com) • [www.northside.com](http://www.northside.com)

## National Cancer Institute (NCI) Awards Northside Hospital Prestigious NCCCP Status



As Georgia's largest community hospital cancer program, Northside is recognized as a national leader in blood and marrow transplantation, women's oncology, urological malignancies and medical oncology. These factors, combined with the advanced clinical care and research typically associated with an academic-based hospital, along with Northside's reputation of providing compassionate care, contributed to its appointment as a National Cancer Institute Community Cancer Centers Program (NCCCP). Joining the network of 30 community cancer centers in the nation, Northside is one of only three programs in the southeastern United States selected to participate in this elite group. The NCCCP

is a network of cancer centers that is expanding cancer research and delivering the latest, most advanced cancer care to more Americans in the communities where they live.

In 2007, the NCI established the NCCCP in recognition of the essential roles that community hospitals play in the health of the American public. The NCI estimates that 85 percent of cancer patients are diagnosed and treated in the community setting. The mission of the NCCCP is to:

- Bring more Americans into a system of high quality cancer care
- Reduce cancer healthcare disparities
- Increase participation in clinical trials
- Improve information sharing among community cancer centers

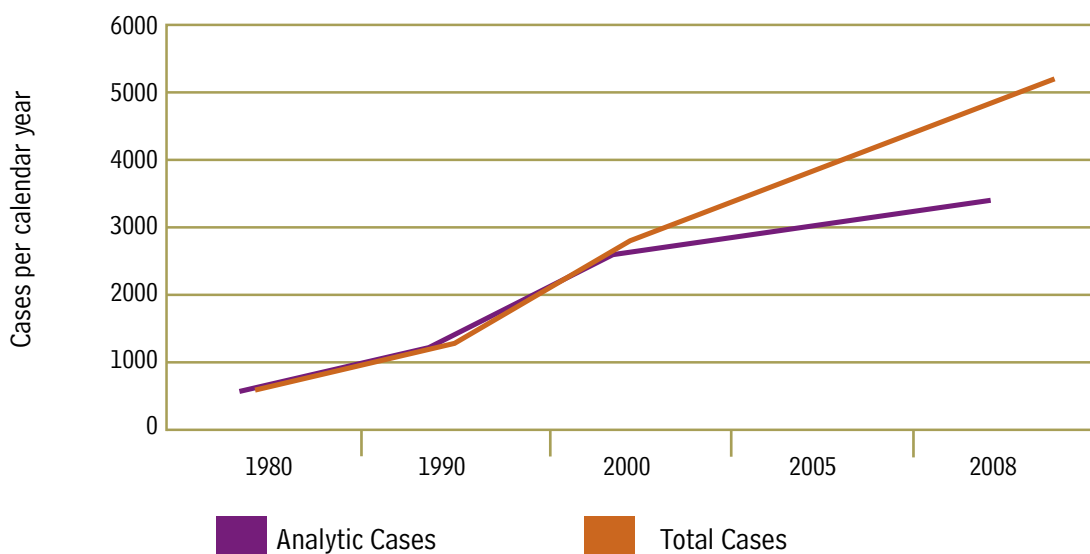
A major factor in receiving NCCCP status was The BMT Program at Northside Hospital's expertise in conducting and coordinating clinical research trials. The program ranks in the top 10 percent of all BMT providers in the country by size. Recent outcome data released by the National Marrow Donor Program (NMDP) indicates that the Northside program has the second best survival following matched unrelated donor allogeneic transplantation for any BMT program in the nation, the best survival by far of any program in the southeastern United States,

*(Continued on next page)*

(Continued from front page)

and the greatest positive variance from predicted survival for any BMT Program in the country (Survival data is provided by the NMDP on their website marrow.org). The NCCCP network serves as a community-based platform to support basic, clinical and population-based research spanning the cancer care continuum – from screening, prevention, diagnosis, and treatment to survivorship and end-of-life care. The NCCCP status and award provides funding to Northside Hospital to further enhance its Cancer Program in the seven NCCCP areas of focus: Quality of Care, Clinical Research, Addressing Disparities, Information Technology, Survivorship and Palliative Care and Patient Advocacy. Northside has further agreed to provide matching funds commensurate with the size of the NCI – NCCCP award to enhance these elements of the program. Significant new staffing is funded by the program.

### NSH Cancer Care Programs Cases by Year (1980 - 2008)



Specifically, the following /enhancements will be implemented:

**Quality of Care:** Enhancement of multidisciplinary cancer care through the use of integrated models, implementation of a Patient Navigation Department, recruitments in the area of tumor registry and genetic counseling.

**Clinical Research:** Northside will further enhance its clinical trials infrastructure to support early-phase clinical trials and a broader range of trials and work with associated community oncology practices to increase clinical trial accrual. Northside will also foster collaboration on clinical trials with other NCCCP sites and NCI Cancer Centers around the nation.

**Disparities:** Strategic Community Outreach & Screening efforts to reach the following disparate populations: Prostate and colorectal cancer in African American men; Breast, GYN, and colorectal cancer in African American women; and Breast and GYN cancer in Hispanic women.

**Information Technology:** Creation of a Patient Treatment Summary (ASCO NCCCP Initiative), facilitation of open access and data sharing of associated oncology practices, enhancements to electronic health records, and adopting tools from NCI's cancer Biomedical Informatics Grid (caBIG).

**Biospecimens:** Implementation of procedures to collect high-quality biospecimens including incorporation of the NCI's Best Practices for Tissue Handling and expands the existing collaboration between Northside and Georgia Tech to provide high quality biospecimens for basic research in cancer biology.

**Survivorship:** Enhancements to provision of Palliative Care, expansion of Survivorship Care Plans, development of Integrated Treatment Summary Data and formalization/enhancement of existing partnerships with The Wellness Community, Camp Hope, Survivors Celebration of Life.

**Advocacy:** Increase relationships with Cancer Advocacy Programs in an effort to enhance the awareness of cancer related activities.

Northside Hospital strongly encourages collaboration with community oncology practices through the facilities generated by the NCCCP award. This will enable patients to stay within the region for specialized care and clinical trials, and assist patients in coping with the emotional and financial burdens often associated with a cancer diagnosis. As part of this program, Northside will assign a nurse navigator to the patient to negotiate them through the process – from paperwork and insurance to scheduling and transportation. Northside Hospital will stay in close contact with community physicians who refer their patient for a service or clinical trial.

In summary, Northside Hospital, as a NCCCP site, will expand staff and implement programs to enhance the level of cancer care provided in the community. The intention of the program is not to duplicate what can routinely be offered in community oncology practices but to partner with those practices to provide advanced cancer services, clinical trials and resources.



*“The NCCCP is a network of cancer centers that is expanding cancer research and delivering the latest, most advanced cancer care to more Americans in the communities where they live. Northside is one of only three hospitals selected in the Southeastern United States to participate in this elite network of cancer centers.”*

## Blood Marrow Transplant Group at NSH Open Protocols

### OPEN STUDIES

NSH 721	NMDP Recipient Consent for Participation in Registry, Research Database, and Research Sample Repository
NSH 747	A Phase II Trial of Non-Myeloablative Conditioning and Transplantation of Partially HLA-Mismatched Bone Marrow for patients with Hematologic Malignancies
NSH 756	Reduced Intensity Allogeneic Stem Cell Transplantation with Matched Unrelated Donors for Patients with Hematologic Malignancies
NSH 810	A Phase II Study of Allogeneic Transplant for Older Patients with AML in First Morphologic Complete Remission Using a Non-Myeloblastic Preparative Regimen; CALGB 100103/ BMT CTN 0502
NSH 850	Phase III Open-Label Randomized Study of Amonafide L-Malate in Combination with Cytarabine compared to Daunorubicin in Combination with Cytarabine in Patients with Secondary AML
NSH 864	NSH 864 A Phase II trial of Myeloablative Conditioning and Transplantation of Partially HLA-Mismatched Peripheral Blood Stem Cells for Patients with Hematologic Malignancies
NSH 877	A Phase II Multicenter Trial of Myeloablative Double Unit Umbilical Cord Blood Transplantation (UCBT) in Adults with Hematologic Malignancy
NSH 887	A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with MMF vs Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD
NSH 888	The Impact of Hematopoietic Stem Cell Transplantation on Primary Caregiver Level of Burden and Distress
NSH 894	A Trial of Single Autologous Transplant with or without Consolidation Therapy versus Tandem Autologous Transplant with Lenalidomide Maintenance for Patients with Multiple Myeloma

### PENDING STUDIES

NSH 886	A Randomized, double-blind, placebo-controlled Phase III study of SGN-35 (brentuximab vedotin) and BSC versus placebo and BSC in the treatment of patients at high risk for residual HL following ASCT
NSH 890	Evaluation of Lenalidomide as Maintenance Therapy after Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma
NSH 893	Phase II Trial Evaluating the Safety and Efficacy of Rituximab as Primary Treatment for Extensive Chronic Graft Versus Host Disease
NSH 898	A Randomised Phase III Study of Elacytarabine vs. Investigator's Choice in Patients with Late Stage Acute Myeloid Leukaemia
NSH 899	A Phase 2a Study of Once-Daily IV Busulfan and Bortezomib Prior to Second Autologous Transplant, in Subjects with Relapsed Myeloma after a First Auto Transplant
NSH 900	Phase II Study of Reduced-Intensity allogeneic stem cell transplant for high-risk CLL
NSH 902	An open-label, phase 2/3, treatment-option protocol of brentuximab vedotin in patients with progression of Hodgkin lymphoma
NSH 903	Reduced-intensity Allogeneic Hematopoietic Cell Transplantation as Second Transplantation for Patients with Disease Relapse or Myelodysplasia after Prior Autologous Transplantation

## Be The Match Foundation® Teams up with The Blood and Marrow Transplant Program at Northside Hospital

Be the Match® is a movement that engages a growing community of people inspired to help patients who need a blood or marrow stem cell transplant from an unrelated donor. The National Marrow Donor Program (NMDP), created Be the Match® to help raise funds that provide financial assistance to patients, cover the costs of typing for donor recruitment and supports clinical research.

The Blood and Marrow Transplant Program at Northside Hospital has developed a partnership with Be the Match.® “As a transplant center we are committed to supporting our patients in all ways possible,” states Dr. Solomon, medical director for the unrelated transplant program at NSH. Through our partnership with Be the Match® our staff provides assistance in organizing recruitment drives, promoting fundraising events, assisting with public awareness, and adding more donors to the registry.

On May 20, 2010, Northside Hospital hosted a bone marrow drive which recruited over 120 donors to the unrelated donor registry. Upcoming events with Be the Match® include:

- Tribute to Partnership Dinner on September 25, 2010 at Agnes Scott College
  - Silent Auction, Donor/Recipient Meeting, Live Music and Dinner
- Tickets or additional information contact- [leslie.kerns@northside.com](mailto:leslie.kerns@northside.com)
- Be the One Run, a 5K, 1K, Tot Trot on October 30, 2010 at Atlantic Station
  - To register, please go to [www.BeTheOneRun.org](http://www.BeTheOneRun.org)



## Northside Hospital's Hematopoietic Stem Cell Processing and Flow Cytometry/Molecular Diagnostic Laboratories

Northside Hospital announced the opening of its new state of the art, 9000 square foot Hematopoietic Stem Cell Processing, Flow Cytometry and Molecular Diagnostic Laboratories. The opening of these new laboratories allows the bone marrow transplant and leukemia programs to provide patients and referring physicians with highly specialized cellular and molecular testing with rapid turn around times.

### Hematopoietic Stem Cell Processing Laboratory

#### Facility Highlights

- HEPA filtered facility with four processing bays
  - Freezer storage facility with on site micro bulk liquid nitrogen supply tanks
  - Environmental monitoring system throughout facility
  - Performs autologous, allogeneic, cord blood and matched unrelated donor processing of cellular therapy products and performs collection of bone marrow
  - Designated National Marrow Donor Program and Gift of Life Registry bone marrow collection facility
  - Licensed by the State of Georgia, registered with the Food and Drug Administration and accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) and Advancing Transfusion and Cellular Therapies Worldwide (AABB)
- (Continued)*



## Staff

- Supervisor with over 25 years of experience in Hematopoietic Stem Cell processing and cryopreservation.
- Quality Assurance and Standards Coordinator with over 15 years experience in cellular therapy processing, regulatory standards and compliance
- Three highly qualified Hematopoietic Stem Cell Specialists with experience in the field of cellular therapy.

## Flow Cytometry and Molecular Diagnostics Laboratories

Irina Grigorieva, PhD, the Director of NSH Flow Cytometry and Molecular Diagnostics Laboratories, is responsible for the overall operation and administration.

Flow Cytometry and Molecular Diagnostics Laboratories are licensed by the Clinical Laboratory Improvement Amendments (CLIA), Georgia Department of Human Resources, and fully accredited by College of American Pathologists (CAP). Flow Cytometry and Molecular Diagnostics Laboratories personnel perform high complexity clinical assays by utilizing innovative equipment and progressive technologies. Both laboratories provide outstanding customer care by assisting clinicians with diagnosis, early detection, patient stratification, drug prescription and prognosis.

## Available Services

### Flow Cytometry:

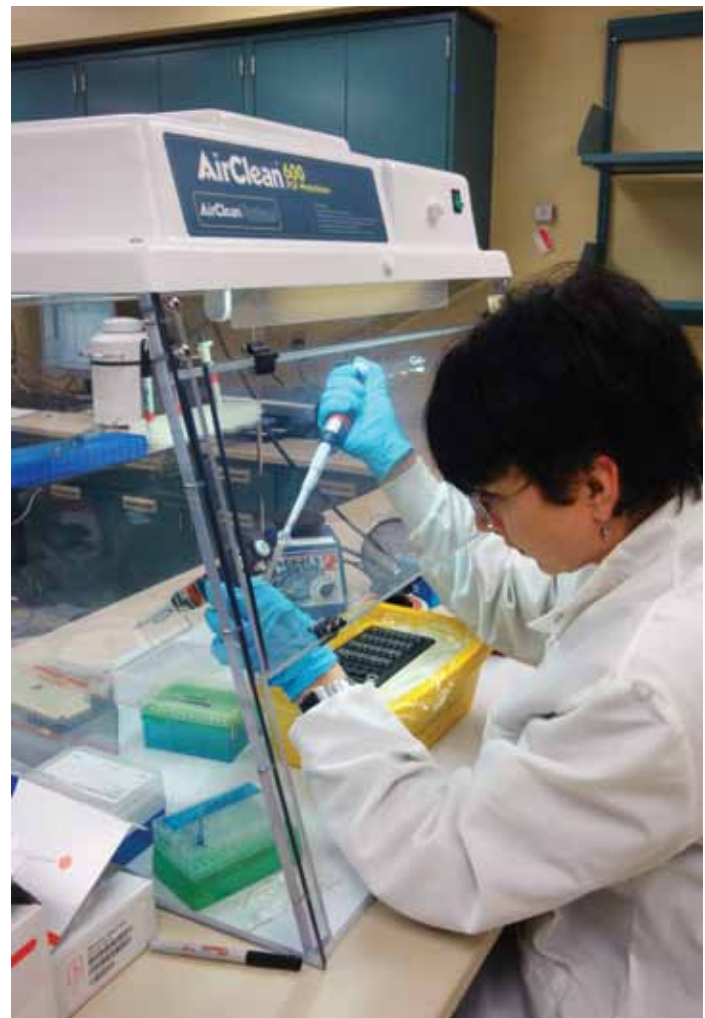
- Six-color immunophenotyping for the evaluation and monitoring of leukemias, lymphomas, multiple myelomas, paroxysmal nocturnal hemoglobinuria (PNH), and other related hematological disorders
- Lymphocyte typing panel for immunocompromised and HIV-positive patients
- Enumeration of CD34-positive precursor stem cells for bone marrow transplant patients

### Molecular Diagnostics:

- Factor II (Prothrombin) gene mutation assay
- Factor V Leiden gene mutation assay
- Quantitation of CMV viral load by real-time PCR
- Microchimerism for transplant patients (final test validation stage)

Molecular Diagnostics Laboratory has developed a strategy for expanding the current test menu by adding various tests in molecular virology, molecular microbiology and molecular genetics.

Please contact Dr. Grigorieva at 404-851-6541 for any questions regarding services provided by NSH Flow Cytometry and Molecular Diagnostics Laboratories.



## Randomized Trial of SGN-35 Antibody Post-Autologous Transplant Open at Northside Hospital

The Blood and Marrow Transplant Program at Northside Hospital will soon be opening a new trial titled “A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of SGN-35 (brentuximab vedotin) and Best Supportive Care (BSC) versus Placebo and BSC in the Treatment of Patients at High Risk of Residual Hodgkin lymphoma (HL) following Autologous Stem Cell Transplant (ASCT).” The primary objective of this trial, sponsored by Seattle Genetics, is to compare progression-free survival (PFS) in patients receiving SGN-35 post-autologous transplant versus patients receiving best supportive care post-autologous transplant.

### Eligibility Criteria:

- Autologous transplant within 30-45 days of enrollment
- High-risk for relapse as defined by:
  - History of refractory HL (defined as patients progressing on or failing to achieve a complete remission following frontline standard chemotherapy (6 to 8 cycles) or a combined modality treatment program)
  - Relapsed or progressive HL that occurs <12 months from the end of frontline therapy
  - Extranodal involvement at the time of pre-ASCT relapse (including extranodal extension of nodal masses into adjacent vital organs)
- Adequate blood and organ function:
  - ANC  $\geq 1000/\mu\text{L}$
  - Platelets  $\geq 50,000/\mu\text{L}$
  - Bilirubin  $\leq 1.5\text{X}$  upper limit of normal (ULN) or  $\leq 3\text{X}$  ULN for patients with Gilbert’s disease
  - Serum creatinine  $\leq 1.5\text{X}$  ULN
  - ALT and AST  $\leq 2.5\text{X}$  ULN
- Must have at a minimum stable disease prior to transplant

### Treatment Plan:

Approximately 322 patients will be enrolled on this study. Patients will be randomized in a 1:1 design. Patients will receive a single infusion of SGN-35/placebo on Day 1 of a 21 day cycle. Patients may receive up to 16 cycles (1 year) of treatment. Progressive disease will require a patient to be removed from study.

### Exclusion Criteria:

- Progressive disease after salvage therapy
- Previous treatment with SGN-35 or allogeneic transplant



### **The Blood and Marrow Transplant Program at Northside Hospital**

The Blood and Marrow Transplant Program at Northside Hospital (BMTNSH) is a collaborative effort between the Blood and Marrow Transplant Group of Georgia (BMTGA) and Northside Hospital (NSH). The program is one of the largest clinical transplant programs in the United States, serving patients undergoing bone marrow/stem cell transplant therapy and providing primary leukemia treatment. Our program has received National Center of Excellence Awards by major insurance companies and is nationally accredited by the following organizations:

- **National Marrow Donor Program (NMDP) • Foundation for Accreditation of Cellular Therapy (FACT)**
- **Advancing Transfusion and Cellular Therapies Worldwide (AABB) • Food and Drug Administration (FDA)**

### **Mission Statement**

The Blood and Marrow Transplant Program at Northside Hospital is committed to being the premier clinical transplant program in Georgia and the Southeast, providing outstanding state-of-the-art care for patients with leukemia and/or undergoing marrow and stem cell transplantation. The Blood and Marrow Transplant Program offers:

- **Autologous Stem Cell Transplants • Related and Unrelated Allogeneic Stem Cell Transplants**
  - **Haploidentical Stem Cell Transplants • Cord Blood Transplants**
  - **Nonmyeloablative / Reduced Intensity Stem Cell Transplants**

The BMT Program operates seven days a week, 24 hours a day, and provides patients with team-based care that includes psychologists, pharmacists, nutritionists and physical therapist

Referrals can be made by calling 404-255-1930, and referrals can be made by a physician or any physician staff member. You will have the option of directly speaking to one of the physicians or a transplant / leukemia coordinator to make the referral. The coordinators will be in contact with your staff to obtain all appropriate records required for the consult and the patient will be contacted directly with the appointment date and time.

**The Blood and Marrow Transplant Program at Northside Hospital • phone: 404-255-1930 • fax: 404-255-1939**