



Carolinan HealthCare System
Levine Cancer Institute

UPDATES IN CANCER FOR CLINICIANS

SUMMER 2014

Phase I Clinical Trials Unit Brings Opportunity to Patients



Edward Kim, MD (left)
*Chair of the Department of Solid Tumor
 Oncology and Investigational Therapeutics*

Steven A. Limentani, MD (right)
*Medical Director, Cancer Trials at
 the Institute*



In the fall of 2012, Levine Cancer Institute, part of Carolinas HealthCare System, opened a Phase I clinical trials unit at its Research and Administrative Headquarters in Charlotte, NC with a focus on first-in-man studies and on ensuring safety, identifying the maximum tolerated dose and pattern of toxicity. Hundreds of patients have been treated in the unit, which features nearly 4,000 square feet of patient space, including eight chairs and four beds for infusion. Of importance, and consistent with our philosophy of decentralizing care, additional Phase 1 units will also open at our Northeast Institute location

and our unit at Roper St Francis Medical Center in Charleston, making it easier for patients to participate in our trials without having to travel long distances. These three units will function as a single entity. The Phase I unit is in close proximity to the 72-chair outpatient infusion clinic, investigational pharmacy and specimen processing lab. The 24-hour unit affords flexibility in patient scheduling and the capability of carrying out complex pharmacokinetic studies. Other attributes of the unit include advanced 12-lead cardiac monitoring, with physician desktop access to telemetry, mobile EKG equipment, synchronized timekeeping, point-of-care charting and integration with

Levine Cancer Institute/Carolinan HealthCare System biorepository. Patients treated in the unit benefit from a higher level of oversight, semi-private treatment pods and prepared meals. When required, Levine Cancer Institute dietitians can order meals to accommodate fed/fasted protocols.

The main purpose of the Phase I unit is to provide clinical and translational research opportunities to patients across the Carolinas. The Phase I unit currently treats patients with a wide variety of cancers including pancreatic, breast, urothelial, bladder and lung who are participating in clinical trials. Investigational agents currently under evaluation include nivolumab (Bristol-Myers Squibb),

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Message from the President of Levine Cancer Institute



Derek Raghavan, MD, PhD
President, Levine Cancer Institute

This edition of Levine Cancer Institute's *Updates in Cancer for Clinicians* reflects the maturation of Levine Cancer Institute, and I hope it is clear that our efforts during the past three years are beginning to have a real impact.

Three years ago, a team led by Steve Limentani, MD, medical director of clinical trials, and Mark King, MPH, technical director of clinical trials, visited other cancer centers known for their Phase I clinical trial record, identified best practices and designed the new unit that is already functioning at our Charlotte branch. While this unit allows patients to experience the safest and most up-to-date approach to Phase I cancer trials, the construction of parallel units at CMC-NorthEast (Concord, NC) and Roper St. Francis Hospital (Charleston, SC), will lead to a three-site entity. This is a revolutionary concept and will make the lives of our patients so much easier, providing all needed facilities for safe delivery of Phase I agents, without the need for long-distance travel. These studies will predominantly have a strong pharmacologic component, with expertise provided from Ram and Mahrukh Ganapathi, who joined us from the Cleveland Clinic three years ago, and Jai Patel, Pharm D, recently recruited from the program at Chapel Hill under Howard McLeod, MD.

For the time being, we have determined the safest approach to delivery of BMT regimens is to focus our work in only two centers. At

Roper St. Francis, George Giles III, MD, has run a successful blood and marrow transplant (BMT) program for several years. As Charlotte is such a major population center for North Carolina, we made the strategic decision to develop a BMT unit at Carolinas Medical Center. Opened recently, this site offers a completely modern 16 bed unit, with ICU capability. Ed Copelan, MD, Belinda Avalos, MD, Jon Gerber, MD, and their team have already done 10 bone marrow transplants, and the unit is filling up rapidly. This fits very well with the panoply of programs addressing the gamut of hematologic malignancies, using innovative treatment regimens, so elegantly summarized by Saad Usmani, MD, FACP, who joined us last year from Bart Barlogie's unit at the University of Arkansas.

That said, our mantra remains "cancer care without walls," and the focus of our other programs is dissemination to our various geographical centers, with shared programs and protocols of clinical management, research and patient support. Jimmy Hwang, MD, formerly the Hematology/Oncology Fellowship Director at the Vince Lombardi Comprehensive Cancer Center at Georgetown University, is developing a series of multi-disciplinary programs in the domain of gastro-intestinal oncology. He is working in concert with our team of medical oncologists throughout Carolinas HealthCare System, and in collaboration with teams of surgeons with expertise in hepatobiliary cancer (led by David Iannitti, MD), colorectal malignancy (Jonathan Salo, MD; Josh Hill, MD, MPH; James North, MD, and Michael Houston, MD, among others), and other upper gastro-intestinal cancers, supported ably by our team of radiation oncologists led by Bob Fraser, MD, and Mary Decker, MD.

One key differentiator of our work at Levine Cancer Institute will be the adherence to evidence-based pathways. Leading this effort is Ed Kim, MD, our chair of solid tumor oncology and investigational therapeutics, who holds the Donald S. Kim Distinguished Chair for Cancer Research. With his oversight, our various multi-disciplinary teams have constructed a series of internet-adapted electronic pathways that reflect level I evidence wherever possible, and focus on the maximum benefit with the least toxicity and cost. With such a large team of oncologists arrayed in multi-disciplinary groups, I believe that the best way to provide consistently state-of-the-art, evidence-based care is to construct clearly defined treatment algorithms that are available to all our physicians. I allocated that complex and demanding task to Dr. Kim, who has done a stellar job in a short time, as you will see from his article.

I hope you will agree that Levine Cancer Institute is providing a unique set of resources to the Carolinas, with regard to standard treatment algorithms, the creation of unique investigator-initiated Phase I and II trials and outstanding programs of patient support and survivorship. Our patients can only benefit from these resources, and I hope you will test us by sharing your complex (and easy) cases, recognizing that they will also derive the benefit of multi-site, multi-disciplinary tumor board discussions that are routinely conducted by video-conferencing.

Sincerely,



We welcome your feedback at LevineCancerInstitute@CarolinasHealthCare.org and look forward to bringing you more news in the future!

Region's First Adult Blood and Marrow Transplant Unit Opens



Edward Copelan, MD, FACP (left)
Chair of the Department of Hematologic Oncology and Blood Disorders

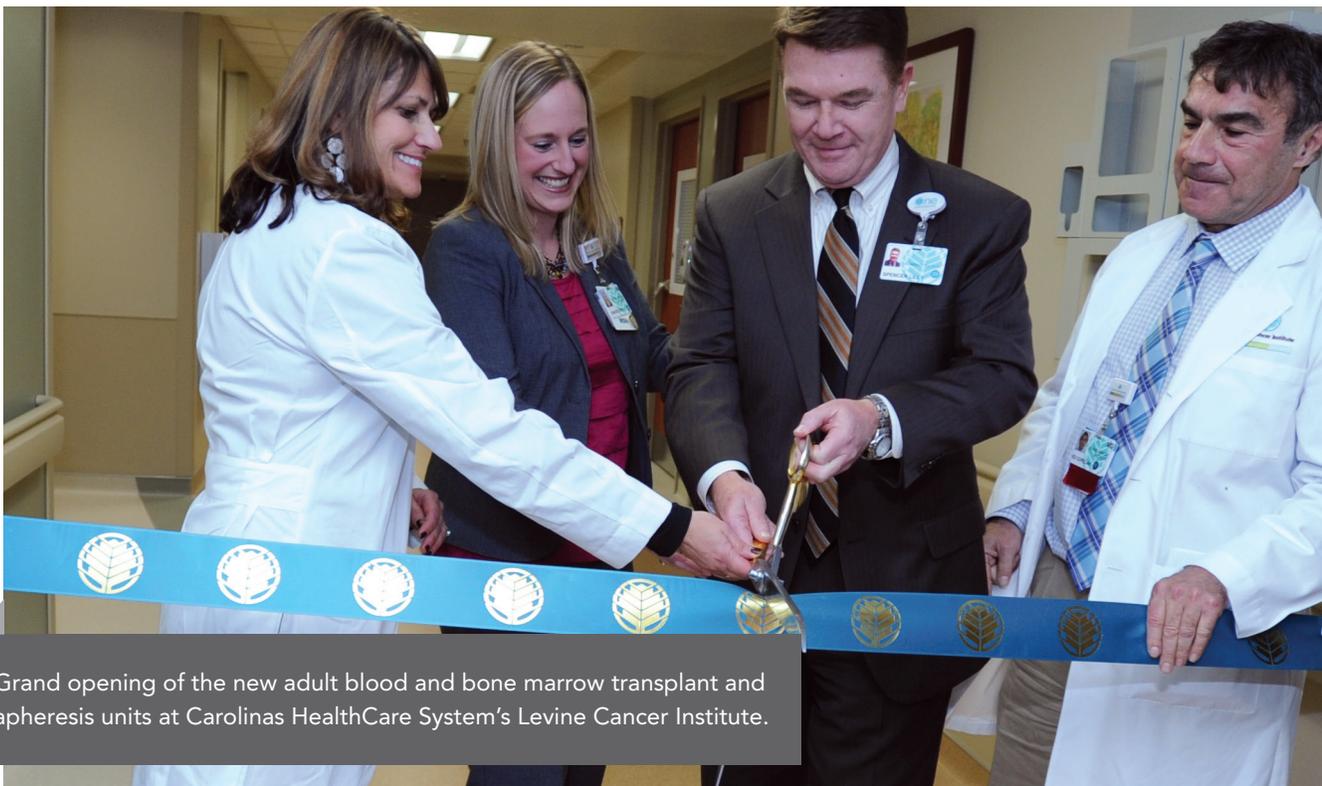


Belinda Avalos, MD (right)
Vice Chair of the Department of Hematologic Oncology and Blood Disorders

Adult patients in the greater Charlotte metropolitan area in need of a hematopoietic cell transplant will no longer have to travel hours away for their transplant. A new 16-bed, state-of-the-art hematologic malignancies unit opened January 22 at Carolinas HealthCare System's Levine Cancer Institute, which brings advanced care closer to home. The new unit, located on the campus of Carolinas Medical

Center in Charlotte, NC, has 16 patient rooms, including four with ICU-capability that are equipped with the virtual ICU technology recently rolled out in Carolinas HealthCare System hospitals. The virtual ICU provides a "second set of eyes" that allows the primary transplant team and remote ICU team to seamlessly manage critically ill patients. The entire unit is a positive-pressure environment with HEPA (high-efficiency particulate absorption) – filtered air that minimizes the risk of infection, particularly from fungal pathogens, and to protect patients who have undergone transplantation or other potent chemotherapy as part of their treatment regimen. In addition to these features, special thought was given to the unique needs of these patients and their families during prolonged hospitalization with the incorporation of an exercise room, laundry room and family lounge into the environmentally

protected unit. An adjacent six-bay apheresis unit and cell processing laboratory will permit donors for both pediatric and adult patients to have their hematopoietic stem cells harvested, processed and cryopreserved until the time of the recipient's transplant. The new transplant unit is part of Levine Cancer Institute's expanding Hematologic Oncology and Blood Disorders program, designed to offer subspecialized care by disease-focused physicians who provide the full spectrum of treatments for patients with leukemia, lymphoma, multiple myeloma, myelodysplasia and other malignant and nonmalignant hematologic disorders. A team of internationally recognized experts, including nine recently recruited to the program, will incorporate cutting-edge clinical trials, and autologous and allogeneic hematopoietic cell transplantation into caring for these patients.



Grand opening of the new adult blood and bone marrow transplant and apheresis units at Carolinas HealthCare System's Levine Cancer Institute.

Multidisciplinary Team Brings Personalized Approach to Colon Cancer Care



Jimmy Hwang, MD
Medical Oncology

Diligent colon cancer screening, surgical resection and adjuvant chemotherapy have improved survival in colorectal cancer. However, a significant proportion of patients will present with or develop metastatic disease. In the early 1990s, metastatic colorectal cancer was thought to be a uniformly fatal disease. For these patients, new surgical, radiation and chemotherapeutic treatments can lead to improvement in quality of life and potential cures. However, it takes considerable expertise to properly select this group of patients who might otherwise be deemed incurable.

At Levine Cancer Institute, we have assembled a highly experienced team of dedicated hepatobiliary and GI surgeons, surgical oncologists, interventional radiologists, radiation oncologists, gastroenterologists and medical oncologists to create a personalized approach to this highly complex disease. We define three populations of patients who present with metastatic colorectal cancer. First,

there is the population who are candidates for surgical resection with the intention for cure. This comprises a minority of patients, perhaps 10 percent of those with metastatic colorectal cancer. A second population would be patients whose disease was once deemed unresectable, who may be now rendered surgically evaluable with newer systemic therapies and modern, advanced surgical techniques. The majority of patients, though, have a large burden of liver disease or widely metastatic disease that are not amenable to resection, and in whom the primary goal of therapy is control of the disease and symptoms, and prolonging life.

For patients with relatively limited liver or lung metastasis, aggressive treatment can lead to potential cures. In the past, this approach was a difficult path for patients to tolerate. However, at Levine Cancer Institute, our dedicated hepatobiliary surgeons have pioneered techniques to make liver-directed therapy available to a greater number of patients. Our surgeons have been recognized globally for cutting-edge ablative techniques, including intra-operative ultrasound and microwave ablation, which decrease operative time and improve tumor kill in the liver. We are continuing this line of work with electroporation for ablation of tumors not amenable to standard techniques. In

addition, we are using robotic techniques to aid in the resection of liver tumors that would otherwise be inoperable.

For those with traditionally unresectable metastasis, advances in biotherapy, chemotherapy and radioembolization have created new opportunities. Our medical oncologists use combinations of biotherapy and chemotherapy to reduce the size of large tumors, which may make resection or ablation possible. Another promising treatment is the use of radioembolization with SIR-Spheres. We were one of a few select United States sites to participate in the SIRTEX trial, which combined radioembolization and systemic chemotherapy to treat patients with colorectal cancer metastatic to the liver. Our participation led to a larger national trial to determine whether this combination of therapies will allow greater disease control and survival compared to traditional therapy alone.

This challenging group of patients benefit from multidisciplinary evaluation at a center with a high level of experience with liver metastasis. Our physicians share clinic space and participate in multidisciplinary conferences to ensure the best coordinated care and patient outcomes. We want to ensure that every option is explored for our patients, to optimize their outcomes.

Clinical Pathways Ensures Quality Cancer Care Across the Carolinas



Edward Kim, MD
*Chair of the Department of Solid Tumor
 Oncology and Investigational Therapeutics*

Levine Cancer Institute and Carolinas HealthCare System are changing the course of cancer care with the development of a “cancer center without walls,” a System-wide approach at providing consistent, scientifically sound cancer care to the roughly 14,000 new cancer patients each year across the Carolinas. The cornerstone to this approach is the development and implementation of locally developed clinical care pathways, referred to as Electronically Accessible Pathways (EAPathways).

Over the past year, Levine Cancer Institute faculty physicians across two states have joined together in close-knit, disease-specific sections to develop the EAPathways for community-based oncologists System-wide that outline clinical treatment pathways, palliative care and social work pathways, and, importantly, the real-time availability of clinical trials. The sections have put together pathways for more than 15 solid tumors, including bladder, breast, colorectal, esophageal, gastric, hepatocellular, kidney, lung (small and non-small cell), melanoma, neuroendocrine, prostate, rectal, testis, pancreas, sarcoma and

spinal tumors. Pathways also have been developed by sections for hematologic malignancies, including acute chronic myeloid leukemia.

Available to clinicians via the Carolinas HealthCare System intranet, the EAPathways software application allows physicians 24-hour access to the preferred treatment pathways for a patient with a particular cancer type, either on their desktop or mobile device. Physicians are required to access the application via secure login and register their patients in either a treatment pathway or clinical trial. All clinical trials are displayed prominently alongside corresponding pathways and trial enrollment is highly encouraged. Physicians will be able to view information on a trial, including a one-page summary, the informed consent and the protocol, directly from the EAPathways system. Once the patient is registered on a pathway, the physician will be able to access a printable packet of information for the pathway or trial that includes chemotherapy orders, teaching sheets, drug toxicity forms, a calendar and drug prescriptions. For complex cases in which a pathway or trial is not available, physicians will be required to document the reason for non-pathway/trial use. Later this year, Levine Cancer Institute will require a 70 percent compliance rate with pathways or trial enrollment for all faculty physicians, with the caveat that deviations from the pathways will be allowed for a set of justified causes.

The advantages of the EAPathways to patients and

physicians are plentiful. First and foremost, physicians will have real-time access to open clinical trials. If the trial is open to accrual, it is displayed alongside the pathway options. If the trial is closed, it will not be visible. Thus, physicians will not have to spend time researching what trials are available for each patient. Physicians can also send an email to the study nurse or coordinator, directly from the EAPathways tool, to request evaluation of potential trial patients. Having clinical trials incorporated into the EAPathways system greatly reduces time and effort for staff enrolling the patient onto the trial. Just as importantly, the EAPathways software will provide general community oncologists with a set of preferred treatment pathways, enabling them to provide the same clinical care options as a specialty oncologist. The palliative care pathways will also allow physicians to treat the side effects of cancer therapy consistently, with direction on when to refer patients to palliative care specialists.

Providing oncologists at rural locations across the Carolinas with the EAPathways will largely standardize cancer treatment for patients of Carolinas HealthCare System and will provide them, closer to home, the same quality healthcare they would receive at the larger, metropolitan cancer facility. Equal care for cancer patients and access to novel clinical trials, regardless of geographic location, is of utmost importance to this cancer center without walls.

Developing Survivorship Care Plans and Transition Visits at Levine Cancer Institute



Wendy Gram Brick, MD (left)
Medical Oncology



Chasse Bailey-Dorton, MD (right)
Oncology/Survivorship

Natalie Garces, BSN, OCN
(not pictured)
Survivorship Coordinator

Beth York, MA, LPC (not pictured)
Director, Survivorship and Integrative Oncology

Traditionally, post-treatment survivorship care has been a neglected phase in the cancer continuum. As survivors leave their “safety net” of frequent, regular interactions with their oncology treatment team, they are often left feeling unguided and unsure of their future. Some survivors may have little to no social support outside of their oncology treatment team. Numerous professional and service organizations now call for an increased focus on planning and coordination of post treatment survivorship care between the oncologist, the patient and the primary care physician.

The foundation of a comprehensive post treatment survivorship program is the multidisciplinary oncology treatment team. Additionally, experts in fertility preservation, genetics, social work, counseling, nutrition, palliative medicine, rehabilitation, psychiatry and integrative oncology are needed. Levine Cancer Institute offers a diverse group of survivorship programs, classes and services at multiple locations across our large two-state network. While most services are provided in a traditional manner (i.e. in person), the key to continued success is leveraging technology to improve efficiency and enhance communication. A prime example is our use of telemedicine for genetics, nutrition and psychosocial services throughout our regional sites.

Three major challenges of executing coordinated survivorship care are the potential lack of survivorship focused knowledge of the healthcare team; the lack of an effective mechanism to consistently, systematically and efficiently ensure that this communication takes place; and the lack of a reliable, cost-effective

strategy for delivering survivorship care. To meet these challenges, Levine Cancer Institute developed a set of up-to-date clinical pathway guidelines to ensure physicians across our network provide consistent, reliable and cost-effective cancer care while fostering communication. We have incorporated aspects of post treatment survivorship care into those guidelines aimed at increasing quality of life and survival.

A formal process to consistently and systematically address post treatment needs relies on the Survivorship Transition Visit. Every patient completing active cancer treatment will have an extended clinic visit to review their summary of treatment and detailed plan for survivorship care. This visit will occur with the survivor’s oncology provider, at the site where the patient is treated. At the end of the visit, the survivor will leave with a written treatment summary and survivorship care plan. The plan will also be forwarded to the survivor’s primary care physician. Key elements to the survivorship care plan include management of long term treatment effects and late onset side effects, surveillance for recurrence, screening for new cancers and recommendations for lifestyle activities that can affect the survivor’s morbidity and mortality.

Levine Cancer Institute piloted this survivorship program for breast cancer patients and their transition visits. The doctors referred the patients appropriately and the program utilizes advanced care practitioners to deliver care. The success of this pilot has led to expansion of the program throughout the System and succeeds in delivering efficient and personalized care.

Comprehensive Care for Hematologic Malignancies



Saad Zafar Usmani, MD, FACP
Hematologic Oncology

The Department of Hematologic Oncology and Blood Disorders at Levine Care Institute is the first and only comprehensive, full-service program for patients with hematologic malignancies and other blood disorders in the greater Charlotte area. The Bone Marrow Transplant unit officially opened January 16, 2014 at the research and administrative headquarters of Levine Cancer Institute in Charlotte, NC. Under the leadership of Drs. Edward Copelan and Belinda Avalos, the emphasis of the program is to provide cutting-edge care for patients with all blood disorders through improved diagnostics, therapy and long-term management. The program is divided into five sections: bone marrow transplant, leukemia, lymphoma, myeloma and non-malignant hematology. There are 13 dedicated hematologists, and each section is under the leadership of subspecialty experts. Since the launch of the clinical research program in July 2013, the following clinical trials for hematologic malignancies have already been opened at Levine Cancer Institute with several more trials slated to open by spring of 2014.

Open Trials

Leukemia/Myelodysplasia

- Sunesis VOS-AML-301: A Phase 3, Randomized, Controlled, Double-Blind, Multinational Clinical Study of the Efficacy and Safety of Vosaroxin and Cytarabine Versus Placebo and Cytarabine in Patients With First Relapsed or Refractory Acute Myeloid Leukemia (VALOR).
- Celgene Phase III Oral Best Supportive Care +/- Oral Azacytidine for Low Risk MDS

Lymphoma

- CALGB 50801: A Phase II Trial of Response-Adapted Therapy based on Positron Emission Tomography (PET) for Bulky Stage I and Stage II Classical Hodgkin Lymphoma (HL)

Multiple Myeloma (MM)

- SWOG 1211 Phase I/II Transplant Ineligible High-Risk Newly Diagnosed MM: RVD +/- Elotuzumab (anti-CS1 mab)
- Janssen Phase II Trial for MM with > 3 Prior Lines of Therapy (Including a Proteasome Inhibitor and IMiD), or are Double Refractory to a Proteasome Inhibitor and an IMiD: Daratumumab (anti-CD38 mab)
- Onyx Phase Ib/III for MM with > 2 Prior Lines of Therapy: Oprozomib (oral proteasome inhibitor from Carfilzomib family) + Pomalidomide + Dexamethasone.
- ArrayBioPharma Randomized Phase II for MM with > 2 Prior Lines of Therapy: Carfilzomib +/- ARRY-520 (kinesin spindle protein inhibitor)

Forthcoming Trials

Leukemia/Myelodysplasia

- Pfizer Phase III Of Inotuzumab Ozogamicin (anti-CD22) Versus Investigator's Choice Of Chemotherapy In Patients With Relapsed Or Refractory Acute Lymphoblastic Leukemia

Lymphoma

- Janssen Phase III for Newly Diagnosed Non-GCB Diffuse Large B Cell Lymphoma: R-CHOP +/- Ibrutinib (oral Bruton-kinase inhibitor)
- Millennium Phase III for Newly Diagnosed Hodgkin's Lymphoma: ABVD versus AVD + Brentuximab Vedotin
- Janssen Phase III for Relapsed Mantle Cell Lymphoma: Bendamustine/ Rituximab +/- Ibrutinib (oral Bruton-kinase inhibitor)
- BMS Phase II for Relapsed Diffuse Large B Cell Lymphoma: Nivolumab (anti-PD1 mab)
- Pharmacyclics Phase Ib/II for Relapsed Diffuse Large B Cell Lymphoma: Ibrutinib + of Lenalidomide +/- Rituximab

Multiple Myeloma (MM)

- Phase IIIb, Randomized Trial of Lenalidomide Maintenance Therapy versus Observation Following Non-IMiD Based Induction Therapy in Newly Diagnosed MM.
- Janssen Phase II Study for MM > 1 Prior Line(s) of Therapy: Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs. Lenalidomide and Dexamethasone (Rd)
- Pharmacyclics Phase I/IIb for MM with > 2 Prior Lines of Therapy: Carfilzomib + Ibrutinib (oral Bruton-kinase inhibitor)
- 4 Phase I/II Investigator-Initiated Clinical Trials

Levine Cancer Institute Phase I Clinical Trials Unit *continued from page 1*

ALT-801 (Altor Bioscience) and AZD9291 (AstraZeneca). A number of trials evaluating the use of other agents across both solid and hematologic cancers are slated to open to accrual in early 2014. Initially all patients must be referred to a designated Levine Cancer Institute Phase I investigator for treatment at Levine Cancer Institute's research and administrative headquarters, but we anticipate two other sites opening in 2014/2015 in Charleston, SC and Concord, NC. Phase I clinical trials are reviewed by a central institutional review board and can be activated within three months. This is especially important for early phase studies that open and close to accrual quickly. In addition to trial sponsor-required assays, Levine Cancer Institute investigators are working to conduct broad, comprehensive biomarker testing on all Phase I trial patients.

A state-of-the-art specimen processing and storage lab is adjacent to the Phase I unit. The lab is staffed by full-time technician Shay Rogers, CPT, who processes and stores blood and serum samples for clinical trials. The lab contains two ambient and three refrigerated centrifuges, two -80°C freezers, a -20°C freezer and a 40°F refrigerator. The entire Phase I unit is equipped with an emergency generator in the event of a power outage. Specimen storage units are also on generator-backup, and staff have access to remote temperature

and equipment alarm status through the web-based MetaSys Monitoring system. These systems guard against the potential loss of research samples during a power outage or mechanical failure. Dedicated air handling systems for the lab ensure the stability of the room temperature. The Phase I unit lab has the capacity to store more than 800 samples on site and will be fully integrated with the lab information management system used by Levine Cancer Institute and Carolinas HealthCare System biorepository in 2014. Barcode labeling and scanning of specimens will facilitate proper identification and chain of custody records as samples are transferred from the Phase I unit to trial sponsors and Carolinas HealthCare System biorepository in Mint Hill, NC.

The Phase I unit is staffed with a dedicated, full-time pharmacist and nurse practitioner. Jai Patel, PharmD, chief of pharmacology research, was recruited from the UNC Institute for Pharmacogenomics and Individualized Therapy and the UNC Eshelman School of Pharmacy in 2013. Dr. Patel oversees the clinical trials pharmacology lab and develops proof of concept, investigator initiated studies involving pharmacokinetics, pharmacodynamics and pharmacogenomics. Jennifer Gray, ACNP-BC, also joined the team in 2013 as the unit's dedicated, midlevel provider. Dr.

Patel and Gray oversee specimen collection within the unit. In addition, six ACLS-certified nurses care for Phase I patients. Through a unique relationship with MedCenter Air, an advanced life support specialist is stationed in the unit while Phase I trial patients are treated.

The Phase I team at Levine Cancer Institute's Research and Administrative headquarters in Charlotte is a broad, multidisciplinary team of professionals working together to bring the most promising, scientifically sound Phase I clinical trials to the Charlotte region and beyond. Physician-investigators, clinic and infusion nurses, and research data and regulatory teams from across Levine Cancer Institute's enterprise meet monthly to discuss proposed trial protocols, review trial accrual, review safety concerns and provide updates on trial progress. Additional meetings are convened as needed to address any emergent issues or to expedite review of new Phase I trials. Additional Phase I clinicians will be added to the team as the new units open up in Charleston and Concord.

To search for open trials at Levine Cancer Institute, visit CarolinasHealthCare.org/Adult-And-Pediatric-Oncology-Clinical-Trials. If you have a patient who may be eligible for a Phase I clinical trial, please contact the study coordinator or the Phase I clinical trials supervisor, Angela Anderson at 980-442-2365.

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