

## Greenville Gives Cancer Care a New Name

September 01, 2011

By Brandy Woods Snow

Cancer. The mere mention of the word is enough to send shivers up your spine. Chances are we have known dear friends and/or loved ones affected by this disease; perhaps we've experienced it ourselves. According to a 2010 Cancer Facts & Figures report generated by the American Cancer Society, in South Carolina alone there were an estimated 23,240 new cancer cases reported last year in comparison to a U.S. estimated total of 1,529,560 cases. Also in 2010, there were an estimated 9,180 cancer deaths in the state and 569,490 throughout the U.S. The toll on human life caused by cancer isn't pretty and neither is the financial cost. According to the Greenville County Cancer Profile report generated by DHEC in September 2010, the overall annual cost of cancer in the county was estimated at \$338 million. Still, Upstate residents, as well as citizens nationwide and abroad, have a reason to hope and a reason to celebrate as ground-breaking new technologies are continuing to erase the borders of what was known and accepted about cancer and its treatments. Better yet – much of it is happening right here in Greenville.

Our city is quickly being recognized nationally and internationally for its cutting-edge research and innovative approach to dissecting the genetic make-up of cancer cells in order to deliver a more targeted, individualized therapy. Cancer treatments are not a "shot-in-the-dark" or "one-size-fits-all" treatment plan, but rather a strategically mapped out therapy specifically targeted to attack the very core of the disease – and with very promising results already being witnessed and documented. Collaborative efforts between clinicians, academia and private corporations are bringing significant advancements in treatment and care while others are fine-tuning later Phase II and III clinical trials for FDA approval. Some are already implementing programs that seek to address and fulfill the full realm of patient needs, from the physical to the spiritual and everywhere in between. The personalized therapies and programs being instituted here in Greenville are breaking the mold on previous standards of care, and as residents, we are lucky to be with them on the forefront of such significant breakthroughs.

### Greenville Hospital System University Medical Center/ITOR

What began as a dream in 2004 of bringing a cutting-edge cancer destination to Greenville focused on translational research and personalized medicine in order to bring new drug therapies to the patient with utmost expediency, culminated in October of last year in the development of the Institute of Translational Oncology Research (ITOR) of Greenville Hospital System University Medical Center (GHS). With a Phase I Clinical Research Unit, a Biorepository services platform and advanced genomic capabilities, ITOR has garnered both national and international attention for its facilitation of cutting-edge research in bringing highly personalized cancer therapies directly to the patient in the safest and quickest manner.

"We're taking cancer therapies to an individual and highly personal level for our patients," says Dr. Jeff Edenfield. "For instance, if a female patient comes to us with breast cancer, we aren't focused on how to treat cancer, we're focused on how to treat her cancer. By developing a system where we analyze and implement targeted therapies best-suited to an individual's cancer's molecular composition, we can ensure the most optimal performance in fighting their cancer."



Since last year's announcement, ITOR has reached significant milestones in 2011 with the continued focus on oncology drug development and the biorepository. ITOR continues to develop and cultivate large pharmaceutical partnerships with the likes of Novartis and Amgen but is also recruiting smaller, more targeted pharmaceutical companies such as Threshold and Mersana. ITOR hopes to bring more experimental drugs into the Upstate at a quicker pace while improving the quality of life for its oncology patients. The biorepository continues to harvest tissue for early drug development and validate new diagnostic tools.

"We've probably completed 500 analyses with some astounding results, often discovering an available pathway that may not have been previously considered," says Edenfield. "We are working with a passion for developing new cancer drugs that specifically target what's broken in cells, and these advancements will lead to more cost effective and more efficient clinical trials."

"ITOR represents a 'unique trifecta' of clinicians, academic researchers and industry partners converging in one place to promote translational medicine," says Sam Konduros, ITOR's business development director. "Through the work of the clinical research unit, we are seeing many late-stage cancer patients find ways to effectively manage and battle the disease, sometimes resulting in an extension in their quality of life for years."

He adds, "ITOR has completed more than 12 first-in-human trials and typically has 25-30 active trials at any given moment. This is in addition to the constant stream of newly-committed trials that have not yet launched, plus a substantial number of follow-up trials where no new patients are being enrolled but we are continuing to monitor the progress of surviving patients. With approximately 16 different pharmaceutical partners sponsoring open trials at this time and the constant influx of new, exciting trials and interest from pharmaceutical companies, the Clinical Research Unit's track record speaks for itself and is making a real difference in the lives of patients."

In June 2011, the ITOR Innovation Zone, a 20,000-square-foot laboratory space fully outfitted for ITOR's partners, was publicly announced. This unique research lab environment brings industry partners, clinicians and academia together in one location to promote the most effective and efficient collaboration.

"ITOR is also continuing on its economic development mission, acting as a catalyst in attracting new innovative companies to the area, from small start-ups to larger, more established corporations," says Konduros. "We're aggressively moving forward in building the ITOR brand both across the U.S. and internationally."

**KIYATEC**, which specializes in 3D cell culture technology, was announced as the first private company to locate within the Innovation Zone. CEO Matt Gevaert says the relationship between Kiyatec and ITOR is an excellent fit. "Our 3D cell cultures create a more natural cell environment that allows for more accurate modeling of complex human biology, of you and me. With better models, cancer doctors can benefit in two ways. Using 3D cell culture, better prediction of which compounds are both safe and effective before administering them will translate to fewer drug failures in clinical trials – the patients and their physicians spend less time on paths that eventually prove unfruitful. Then, with respect to approved drugs, we're exploring how 3D cell culture can give clinicians a more comprehensive picture of how a drug therapy may affect an individual patient. This creates a win-win-win, saving patients from potential drug toxicity, saving the time and cost of an ineffective therapy option, and even potentially reducing the number of animals used in this kind of research."

Lab21, a rapidly growing healthcare diagnostics business, provides state-of-the-art molecular diagnostic products and services in personalized medicine to a wide range of healthcare organizations, clinical laboratories and pharmaceutical companies worldwide. Lab21 opened their US headquarters in Greenville in 2010 and just opened a clinical laboratory in the Next Innovation Center on Church Street. Lab21 also recently established a product development footprint in the ITOR Innovation Zone. "This is a unique, collaborative environment purpose built to accelerate a transition to personalized and more effective cancer treatment," says Michael Bolick, president. "We are excited to have our Selah Dots® product development effort located in the Innovation Zone. We greatly value the close proximity of the ITOR biorepository and day-to-day interaction with translationally-minded clinicians and other innovative collaborators."

"ITOR has been distinguished by its ability to move quickly amidst intense and dynamic collaboration between academia, research, clinicians and pharmaceutical partners in order to uncover new advancements and drug therapies and swiftly get those into action with our patients," says Edenfield. "This level of translational medicine in a community cancer program in a city the size of Greenville? It's not usual and not easy to find but it's what makes Greenville's story so remarkable." Looking

ahead, Konduros says the ITOR team is currently in the midst of mapping out a comprehensive five-year plan that will include some major initiatives focused on the implementation of new technologies and infrastructure, as well as increased advancements in molecular profiling to propel the consortium further. "Over the next six months to year, we expect to make significant strides with ITOR's tissue bank, continue to attract the attention of top pharmaceutical companies and their experimental trials, and work with a variety of technology companies in showcasing their equipment in our unique clinical environment – all to the benefit of our patients."

### **Cancer Center of the Carolinas**

Initially recognized by the National Cancer Institute (NCI) in 1995 as a Community Clinical Oncology Program (CCOP), the oncology group took on the name Cancer Centers of the Carolinas (CCC) and extended its practice capabilities to include radiation oncology, diagnostic radiology, clinical trials and research and stem cell transplantation. Today, CCC treats more than 6,000 new patients annually.

As a CCOP, CCC has access to a number of large national-based trials. Dr. Jeffrey Giguere, principal investigator of the Greenville CCOP, says CCC specializes in Phase II and Phase III trials, taking new "proven" trials and putting them into practice with a larger pool of patients, doing final phase work in order to ensure FDA approval of new therapies. "CCC's role isn't always 'glamorous' or 'sexy' but it's necessary and essential," says Dr. Giguere. "Our later-stage trials serve as the proving ground for initial results from primary testing, and here is where 'the rubber meets the road.'"

On average nationally, only 3 percent of cancer patients enter into a clinical study, while at CCC, the average is around 12-13 percent participating. Dr. Giguere says the clinical trials underway at CCC point to a paradigm shift in the way cancer treatments are evaluated and implemented. In light of the rapidly growing field of genomic research, patients are not being treated based on tumor type, but rather the cancer's unique genetic profile. Dr. Giguere specifically notes two trials in breast and lung cancers that have shown remarkable results to what were once considered highly-resistant and aggressive strains. The particular mutation present in the lung cancer trial is only seen in 7 percent of cases but with the advent of a drug therapy made to target this mutation specifically, trial patients began to feel better and see positive results within a week's time. Dr. Giguere says that FDA approval for the new drug is expected shortly.

CCC works closely with notable organizations including MD Anderson Cancer Center and the University of Rochester on a host of clinical trials and is also heavily involved on symptom management, where they actively investigate and bring to patients the best methods to efficiently manage the side effects of treatment, including diarrhea, neuropathy and cognitive brain issues, to name a few.

As of late, CCC has been working to integrate complementary therapies for a more holistic approach to cancer treatment and rehabilitation, incorporating practices such as yoga and therapeutic massage. In two specific studies involving colon and breast cancer noted by Dr. Giguere, patients implementing an exercise regimen in addition to treatment showed a marked decrease of recurrence and an increased rate of survival. Such oncology rehab programs are showing a decrease in such risks when initiated after the initial treatment.

"We have a responsibility to society in conducting thorough and adequate testing of promising new advancements in the treatment of cancer. Sometimes in clinical trials, new doesn't always mean better, and these are the types of answers and information we seek to provide through our Phase II and III work."

"CCC is not a profit-centered organization, and it is our mission to better people's lives through our clinical research and collaboration with other local hospitals. Not every study is a winner – but some are – and proving those creates the most benefit for our patients."

### **Bon Secours St. Francis Health System**

At St. Francis, Dr. Gary Spitzer with Upstate Oncology Associates says the health system's commitment to innovative clinical research and a more acute knowledge and understanding of cancer itself is ushering in a paradigm shift in treatment options and the development of more relevant drug therapies.

"It is St. Francis' goal to constantly grow and recruit premier oncologists that can conduct research and manage the needs of patients above and beyond the typical standards of care. Our oncologists are integrated into the hospital setting so they seamlessly become part of the total patient health," says Dr. Spitzer. "The quality of people hired over the last two years is phenomenal, and we are seeing a tremendous amount of activity generated in clinical research in this short amount of time."

Nowhere is this more evident than in the story of Sergii Gomeniuk, a 20-year-old college student from the Ukraine who traveled to Greenville to enroll in a clinical trial, with the hope of finding some ammunition in fighting the cancer plaguing his lymphatic system. Diagnosed with Hodgkin's Lymphoma, Gomeniuk underwent chemotherapy and even stem cell transplant in his own country to no avail, and the doctors had left him with no other options. That is, until, he hooked up with non-profit group Advita that helped place him in the St. Francis clinical trial of a new drug known as Brentuximab, being overseen by Dr. Spitzer and Dr. Frits van Rhee. The promising new drug therapy was highly targeted, attaching a chemotherapeutic agent to an antibody that attaches directly to the cancer cells and destroys them. In some cases, this drug therapy has been able to cause a complete disappearance of the cancer, producing dramatic results. FDA approval on the drug, dubbed Acentris, could be coming in the next few weeks.

Likewise, the Hyperthermic Intraperitoneal Chemotherapy or HIPEC procedure for treatment of advanced abdominal cancers is showing great promise in trial. The procedure begins with the surgical removal of all cancerous tumors within the abdomen followed by a heated chemotherapeutic solution that is placed internally for approximately 90 minutes before removal. Because the heated solution is brought into direct contact with cancer cells in the abdominal cavity, it has shown some tendencies to be more effective while being less toxic to the patient than traditional chemotherapy. Studies conducted with HIPEC for patients with late stage colon cancer have shown a five-year survival rate of up to 40 percent.

"We have to be able to look our patients in the eyes and tell them we are giving our best effort to their treatment and recovery," says Dr. Spitzer. "We are creating a fully integrated process for the patient that looks at their situation holistically, and we treat them as an individual, helping guide their journey through research, navigators, counsel and spiritual care. We're not just administering clinical trials but targeted 'life-saving' therapies."

He adds, "Every cancer patient leaves our facility with a fresh rose – our way of acknowledging that they are an individual and more than just a medical case file. It signifies that we are on this life journey with them, like we are all part of one family."

St. Francis is taking its commitment to the "whole patient" a step further with the implementation of the STAR (Survivorship Training and Rehab) Program, a nationally recognized cancer survivorship program focused on helping survivors heal both physically and emotionally through interaction with specialty caregivers from a pool of disciplines, including physicians, physical and occupational therapists, speech pathologists, dieticians and mental health professionals.

"There are three distinct phases of cancer care: diagnosis, treatment and survivorship," says Lori McKittrick, director of Rehab Services at St. Francis eastside.

Developed by Assistant Harvard Professor and cancer survivor Julie Silver, MD, the STAR program helps patients reduce and manage symptoms while helping them to answer the question "What do I do now?" After an evaluation with a nurse navigator to assess key needs, patients are presented with an individualized care plan to help them on their survivorship journey. St. Francis has been fully accredited in the program for three months with more than 50 employees certified, and it is the first health system in the southeast to attain the accreditation.

"The STAR Survivorship Program is not a one-dimensional view but a multi-faceted perspective on how cancer can affect one's lifestyle and household and showcases how the alignment of mind, body and spirit through nutritional, educational, and physical fitness elements can all combine to improve patient outcome," says Dr. Devena Alston of Upstate Oncology Associates. "After a cancer diagnosis, many patients can feel that life has ended somehow. This program is changing that, providing assistance in symptom management and focusing on the celebration of life by arming patients with the avenues to live life to its fullest."