Dear Friends and Supporters

As we reflect upon 2015, I am proud to report upon the Institute’s achievements in what was truly a landmark year. This newsletter will serve as the first installment of a twice yearly update, to highlight the scientific discovery, innovation and personalized care that have fostered our development into a national leader in neuro-oncology. Our nurses and physicians have an unwavering dedication to our patients, but we are also keenly aware that the tremendous growth of the Institute from its inception in 2012 would be impossible without the generous support of our community. I am confident that our unified efforts will see a cure for brain tumors in our generation, and we should all take pride in our fight to see this dream materialize.

Samuel A. Goldlust, M.D.
Medical Director
The Brain & Spine Institute

Innovation - Offering Our Patients Tomorrow’s Treatments Today

As the only comprehensive brain tumor center in New Jersey, The Brain and Spine Institute at the John Theurer Cancer Center (JTCC) offers an expansive portfolio of clinical trials. Our research in the ground-breaking fields of cancer immunotherapy, oncolytic viruses and blood brain barrier disruption affords us the opportunity to offer hope to patients with even the most aggressive brain tumors who have exhausted standard treatments.

We consistently rank among the top 10 centers nationally in the number of brain tumor clinical trials, and over 80% of our patients participate - 40 fold higher than the national average. We firmly believe that every patient deserves access to tomorrow’s treatments today.

In the following pages we have highlighted three very different but equally promising novel approaches to treat the most common and aggressive brain tumor in adults, glioblastoma (GBM). Perspective on each clinical trial is offered by the physician investigator.

Our center is a place of life and hope, where our physicians are hard at work refining disease treatments and creating novel therapies for you. Our mission is your life.
Phase 1/2 Dose-Escalation Study of TPI 287 in Combination with Bevacizumab in Adults with Recurrent Glioblastoma

INVESTIGATOR: SAMUEL SINGER, M.D.

This multi-center study is open at brain tumor centers around the country, but designed and lead by physicians at JTCC. Recurrent glioblastoma, tumors that have regrown following conventional chemotherapy and radiation, are a particular challenge as there are few effective therapies.

Taxanes are a class of chemotherapy drug, originally derived from the yew tree, and used commonly in breast and lung cancers. Drugs in this family have been known for decades to be effective in killing GBM cells in the laboratory, but as Dr. Kaptain explains on the next page, the real-world difficulty comes in reaching the tumor within the protective blood brain barrier.

However, TPI is different. Subtle changes in molecular structure have engineered the drug to cross the blood brain barrier at concentrations impossible with earlier formulations, and to avoid the brain’s mechanism to expel foreign molecules. The data we recently presented in Philadelphia supported the safety of TPI, and while still early, treated patients have demonstrated unprecedented survival benefit.

Dr. Singer presented his work with TPI at the American Association for Cancer Research Annual Meeting — April 2015, Philadelphia.

Pilot Study of Concomitant NovoTTF-110A and Temozolomide Chemoradiation for Newly Diagnosed Glioblastoma

INVESTIGATOR: SAMUEL A. GOLDLUST, M.D.

In 2015, a large international clinical trial of the device NovoTTF-100A (or Optune™) lead to FDA-approval based upon the most significant improvement in GBM survival in over 30 years. Optune is a portable, battery operated device that creates alternating electric fields in the region of the tumor, by means of arrays worn on the scalp.

The treatment is well tolerated and now proven to extend survival when used in conjunction with the chemotherapy drug temozolomide. Laboratory data indicates that the ability of the device to interrupt mitosis, or division of cancer cells, may be enhanced if the device is used in conjunction with both chemotherapy and radiation. This study, conceived by JTCC physicians, will assess the feasibility of this novel treatment paradigm.

Dr. Goldlust presented his work with NovoTTF-100A at the Annual Meeting of the Society for Neuro-Oncology — November 2015, San Antonio.
One of the greatest challenges we face in brain tumor treatment is the inability to effectively deliver chemotherapy across the blood brain barrier, the brain’s natural shield from foreign substances. The technology used in this study seeks to overcome this dilemma by using the infective power of viruses – not to cause disease – but to harness the power of gene therapy.

In recent years, JTCC has served as one of ten leading centers nationwide to study Toca 511, a virus engineered to selectively infect and deliver a therapeutic gene only to brain tumor cells, while sparing surrounding healthy tissue.

At the time of surgery, Toca 511 is injected into the wall surrounding the tumor cavity to infect any remaining tumor cells. Over the weeks to follow, patients take an oral medication, 5-flucytosine (5-FC), a harmless antifungal drug that readily enters the brain. The infected tumor cells now carry genetic instructions for an enzyme that converts 5-FC into 5-fluorouracil (5-FU), a highly-potent chemotherapy that destroys cancer cells.

Our early studies established that the treatment is safe, well tolerated, and infects tumor cells as intended, and our efforts in 2016 will be dedicated to studying the efficacy of Toca 511 in comparison to traditional chemotherapy.

Dr. Kaptain presented his work with Toca 511 in glioblastoma at the Annual Meeting of the Society for Neuro-Oncology — November 2015, San Antonio.

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**John Theurer Cancer Center Brain and Spine Institute (BSI)**

- **The Caroline Vandemark Fund for Brain and Spine Tumor Research is formed**
- Neuro-oncologist Samuel Singer M.D. and radiation oncologist Brett Lewis, M.D., Ph.D. recruited to BSI.
- **1st Annual Caroline Fund 5K Run raises $45,000**
- 100th patient consents to brain tumor clinical trial
- BSI growth places it among the 10 most productive brain tumor centers in the country by patient volume.
- **2nd Annual Caroline Fund 5K Run raises $100,000**
- Caroline Vandemark Fund for Brain and Spine Tumor Research reaches $400,000
- BSI expected to surpass 200th patient consent in brain tumor clinical trial
The Caroline Vandemark Fund was established in 2013 in honor of an extraordinary young woman whose courageous battle with glioblastoma will forever inspire our pursuit of a cure.

After a remarkable turnout of 500 participants for the 1st Caroline Fund 5k in 2014, the 2nd Annual event in September 2015 exceeded all expectations. Over 100 volunteers and 800 participants joined us in Caldwell, NJ and together we raised over $100,000! We are looking forward to an even bigger showing in 2016.

Glioblastoma survivor and N.J. State Police Officer Bill Fearon also made quite an impact in 2015. Cedar Grove High School raised almost $4,400 for brain and spine tumor research at their annual Hoops for Hope basketball game. Bill’s daughter Elyse plays for Cedar Grove and daughter Jessie sang the national anthem to kick off the event.

Bill’s inspirational spirit and positive attitude have inspired his community, and beyond to join in the fight against GBM.

Upcoming events:
The 3rd Annual Caroline Fund 5k Run is scheduled for September 10th. Please visit: www.carolinefund.org for more information.

You can join us in the fight to cure brain and spine tumors by making a gift to:

HackensackUMC Foundation
Caroline Vandemark Fund
360 Essex St., Suite 301
Hackensack, NJ 07601

For more information please contact, Nancy Kennedy at: 551.996.3523 or nkennedy@HackensackUMC.org

www.HackensackUMCFoundation.org