

Pathway

Physician-Focused News and Resources from Nevada Cancer Institute

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PLUS: REGISTRY
DATA PROVIDES
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Nevada Cancer
INSTITUTE

Research • Treatment • Education



Kenneth A. Foon, M.D.,
is Head of Leukemia
and Interim Director of
Phase I Clinical Trials at
Nevada Cancer Institute



Cutting-edge Technology and Clinical Trials Propel Prostate Cancer Therapies

Nevada Cancer Institute physicians and researchers are using the latest therapies to treat prostate cancer, while also using the latest science knowledge to predict patient outcomes, better influencing therapies and treatment regimens.

Prostate cancer is the leading type of cancer among men in Nevada and will claim an estimated 240 Nevada lives this year alone, according to the American Cancer Society. According to the same report, another 1,700 Nevada men will be diagnosed with prostate cancer this

year; nationally, prostate cancer claims approximately 27,000 lives each year, the vast majority of which are a result of recurrent metastatic disease.

It is imperative that the oncology research community develop simple and inexpensive diagnostic assays to detect specific cancers at the earliest possible time. To this end scientists and clinicians at Nevada Cancer Institute have been working together to identify proteins or peptides in blood, urine, sputum or other body fluids that can distinguish individuals with cancer from those who are cancer free.

Metastatic prostate cancer occurs when tumor cells spread to other locations in the body and grow. Currently, oncologists often have to wait several months before they can determine if specific treatment is beneficial to the patient.

At Nevada Cancer Institute, clinical oncologists and researchers are using the CellSearch™ System to help predict disease progression during therapy.

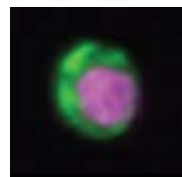
The CellSearch™ System identifies and counts circulating tumor cells (CTCs) in a blood sample to predict progression-free survival and overall survival in patients with metastatic breast, colorectal or prostate cancer, and can do so earlier than the current standard of care. The results of serial testing for CTCs with the CellSearch™ System provide additional information to the oncologist and does so earlier than other currently approved diagnostic modalities, thereby allowing the oncologist to make more-informed patient care decisions.

“We have compared CellSearch™ CTC test results to the standard clinical and biomedical parameters, such as prostate specific antigen (PSA) measured in MPC patients,” said Nicholas J. Vogelzang, M.D., Nevada Cancer Institute director. “A decrease in the number of CTCs is most often associated with patients successfully responding to therapy.

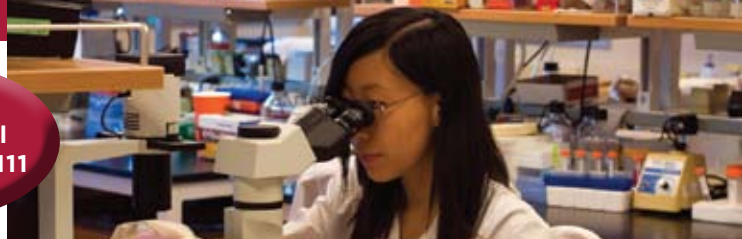
“Further analysis of CTCs may provide information as to the most efficacious treatments for specific individuals.”

The CellSearch™ test works by using antibodies that

Oscar Goodman, M.D., Ph.D., (above left) uses CellSearch™ technology to develop individually tailored patient therapy. The circulating tumor cell (CTC) shows the nucleus of the cell in purple. The green represents cytokeratin. The encapsulated nucleus is a positive CTC identifier.



To refer a
patient call
(702) 822-5111



“Our clinical trials program is a partnership between Nevada Cancer Institute and our community partners, who refer qualified patients for these trials ... It’s about giving their patients more options.” —Oscar Goodman, M.D.

are joined to microscopic iron particles, called ferrofluid. These antibody/ferrofluid combinations attach very specifically to CTCs. Powerful magnets then “pull” the CTCs out of the blood sample, and they are then stained with additional bio-molecules and chemicals so that they can be positively identified as CTCs. The CellSearch™ test differs from the current standard of care because it can accurately predict prognosis much earlier than the prostate specific antigen serum tumor marker test.

“This is truly a case of bench to bedside and even bedside to bench, in that this test does help direct treatment option in our patients,” said Oscar Goodman, M.D., Ph.D., Nevada Cancer Institute clinical oncologist.

“Due to its genetic origin, cancer is a very individual disease. Circulating tumor cells provide a window into an individual patient’s cancer, and analysis of these cells may enable tailored therapy in a bench to bedside manner. Currently, we also are using this to look at all therapies across the spectrum, biological as well as chemotherapy.”

Nevada Cancer Institute stands out in the area of clinical trials because of its clinical trials team—our physicians and researchers serve as the local principal investigator on trials and analyze data, developing new and better ways to treat and give therapies, rather than serving as an extension of an out-of-state research arm.

In addition to the latest in biomarker predictors, Nevada Cancer Institute has a wide range of options for prostate cancer patients, from early stages of diagnosis to later stages when more novel therapy options are often needed. We have more than 20 clinical trials for prostate cancer patients available, from first-in-human, vaccine trials, hormonal therapy, chemotherapy and later-stage trials.

“There really is no standard therapy beyond docetaxel; and many times once that occurs, patients are told there are no other options available,” Dr. Goodman said. “What we can bring to the table beyond the standard of care is to provide patients with an opportunity they wouldn’t normally have.”

One example is the COU-AA-301 Phase III clinical trial available at Nevada Cancer Institute, to which the Institute has accrued some of the largest numbers of patients nationally.

The Phase III trial is a randomized, double-blind, placebo-controlled trial of CB7630 plus prednisone in patients with metastatic castration-resistant prostate cancer who have failed docetaxel-based chemotherapy.

“Our clinical trials program is a partnership between Nevada Cancer Institute and our community partners, who refer qualified patients for these trials,” Goodman said. “It’s about giving their patients more options.”

One option available to patients at Nevada Cancer Institute is the Radiation Oncology Department’s prostate seed implant program, which is accredited by the Seattle Prostate Institute. Nevada Cancer Institute is one of only two radiation oncology practices in Nevada to have this accreditation and affiliation.

The Seattle Prostate Institute has been the leader in prostate brachytherapy worldwide since the early 1990s. It has been shown that the quality of a prostate brachytherapy implants translates to improved patient outcomes. Specific measurable dosimetric endpoints make a difference in cure rates and toxicity.

Radiation clinical trials are also available to patients in the early stage of diagnosis. One such clinical trial available at Nevada Cancer Institute is RTOG 0232, a Phase III study comparing seed implant alone versus external beam radiation plus seed radiation for selected patients with localized/ early stage, intermediate risk, prostate cancer.

Dr. Vogelzang said such a robust clinical trials program with some of the major new drugs that are being developed in the United States and the world, available in southern Nevada, is a boon for patients and community oncologists alike.

“This allows you to provide that care, adding years to people’s lives,” Dr. Vogelzang said. “At the very least, we’re giving patients hope, and that often goes a long way.”

For more information about NVCI’s prostate cancer program, or other oncology programs, please contact Nevada Cancer Institute Director Nicolas J. Vogelzang, M.D., at 822-5200 or nvogelzang@nvcancer.org.

Nevada Cancer Institute Welcomes New Faculty

Nevada Cancer Institute is pleased to announce that **Kenneth A. Foon, M.D.**, has joined Nevada Cancer Institute as head of the Leukemia Section Department of Hematological Malignancies. He is dedicated to developing novel immunological and biological treatment approaches to leukemia and lymphoma.

Before joining Nevada Cancer Institute, Dr. Foon, was deputy director for Clinical Investigations, co-director of the Biological Therapeutics and Hematological Malignancy Programs at the University of Pittsburgh Cancer Institute. He also was professor of Internal Medicine, Division of Hematology and Oncology, University of Pittsburgh, Medical School.

“NVCI’s focus on patient care is really refreshing,” Dr. Foon said. “To have such a humanistic approach and in general to be surrounded by such enthusiasm is a nice fit.

“The opportunity to help grow an institute to serve the needs of the population is not an opportunity that everyone is offered during their careers.”



Dr. Kenneth A. Foon

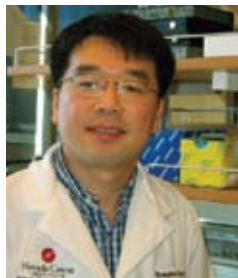
Dr. Foon has a distinguished career. Prior to his tenure at the University of Pittsburgh Cancer Institute, Dr. Foon was director, Clinical Development for Oncology for Abgenix, Inc., in California and clinical professor of Medicine, Department of Internal Medicine, Division of Oncology at Stanford University Medical School.

“Dr. Foon is a world-class expert in hematologic malignancies who has made important discoveries that advance the field and improve patients’ lives,” said Nam Dang, M.D., Ph.D., chief of Hematological Malignancies. “His presence at NVCI will indeed lead to advances

in research and patient care, while it is an indication of the ability of NVCI to attract and recruit top-notch clinician scientists.”

Dr. Foon recently published a major review in the journal *Blood*, authored by F E Craig and K A Foon, titled: Flow cytometric immunophenotyping for hematologic neoplasms (*Blood* 2008;111:3941-3967). Dr. Foon also has a manuscript in press to be published in the *Journal of Clinical Oncology* (KA Foon et al; Chemoimmunotherapy with low dose fludarabine and cyclophosphamide and high dose rituximab FCR-Lite in previously untreated patients with chronic lymphocytic leukemia.)

Dr. Foon has a National Institutes of Health/National Cancer Institute grant to fund research for a Phase III clinical trial using the TriGem anti-idiotypic vaccine for melanoma developed in his laboratories. Dr. Foon is working on developing new protocols for a variety of hematologic malignancies including low-grade lymphomas, chronic lymphocytic leukemia, acute myelogenous leukemia and myelodysplastic syndromes.



Byungwoo Ryu, Ph.D., has joined Nevada Cancer Institute as a faculty member and researcher. Dr. Ryu works in the division of Melanoma, Renal Cancer & Immunotherapy with division head Wolfram Samlowski, M.D. Dr. Ryu comes to NVCI from the Sidney Kimmel Comprehensive Cancer Center at John Hopkins University School of Medicine, Baltimore, where he taught in the Department of Oncology. Previous to becoming an instructor at the School of Medicine, Dr. Ryu served there as a research associate. He received his Ph.D. degree in molecular toxicology from Oregon State University in Corvallis. After earning his degree, Dr. Ryu completed two postdoctoral fellowships, each for two years, one at the National Cancer Institute in Bethesda, MD, and the other at John Hopkins University School of Medicine. Dr. Ryu has published many peer-reviewed research articles in leading cancer journals and periodicals, such as *Molecular Cell Biology*, *Cancer Research* and the *Journal of Biochemical Toxicology*.

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Clinical Trials Program Provides Comprehensive Cancer Treatment

One of the most important parts of Nevada Cancer Institute's research and treatment efforts is our clinical trials program. It has opened 107 trials from May 2005 to October 2008—of which nine were first-in-human trials.

Nevada Cancer Institute offers Phase I, II and III clinical trials. Novel drugs, not otherwise available to patients in Nevada, are made available in these trials.

But what are clinical trials? Very simply, a clinical trial is a research study that evaluates a new way to prevent, diagnose or treat a disease. Clinical trials need the participation of volunteer patients to try these new or modified treatments involving new or known drugs or procedures that have been thoroughly researched in successful laboratory studies, and further reviewed and approved to be tested in humans by the FDA.

A clinical trial program helps physicians and researchers determine the safety and effectiveness of new therapies. Clinical trials are important in developing new treatments for diseases, like cancer. Many of today's standard of care cancer treatments that are accepted and widely used by medical experts are the results of previous clinical trials.

What is important about Nevada Cancer Institute's clinical trials program is that it is the only Phase I program for oncology available in Las Vegas. While some other centers, local physicians, and hospitals in southern Nevada will claim that they have Phase I clinical trials, they actually are affiliated with clinical trial programs at out-of-state universities. The complete process does not take place in Las Vegas, so the results are sent out of state.

Phase I clinical trials program at Nevada Cancer Institute are conducted at our flagship facility. Our doctors work with pharmaceutical companies as well as design investigator-initiated trials which are sponsored by private and/or public grant sources. In addition to

these trials, Nevada Cancer Institute also participates in trials sponsored by the National Cancer Institute.

Nevada Cancer Institute is proud to offer to residents of our state access to multi-specialty tumor trials in their fight against cancer.

Nevada Cancer Institute's clinical trials research is at the heart of the Institute's work toward finding a cure. The program is built on offering current standard of care to patients and the opportunity to access novel agents, receiving treatment in addition to standard of care. Our research is conducted in an efficient, ethical and fiscally responsible manner and approved by responsible Institutional Review Boards.

The Clinical Trials Office includes clinical research nurses, clinical research coordinators, research data coordinators, regulatory coordinators, and

Clinical Trials Activities at Nevada Cancer Institute

(107 trials opened May 2005-Oct. 7, 2008)

- 24 Phase I trials

- 43 Phase I/II, II trials

- 31 Phase II/III, III trials

- 9 First-in-human trials

administrative support personnel that monitor the success of each trial conducted at the Institute.

Why are clinical trials so important? Besides offering a new treatment and new hope to a patient to defeat their cancer, it is an opportunity to contribute to a research effort that could help other cancer patients now and in the future. If the clinical trial proves a new cancer therapy is more effective than the current treatment, patients in the clinical trial receive the benefit of the new treatment before it becomes available to the world. A patient at Nevada Cancer Institute can play an important role in helping to find new and better treatments for cancer for humanity.

For information about Nevada Cancer Institute's Clinical Trials program, please contact Interim CTO Director, Kenneth A. Foon, M.D., at 822-5572 or kfoon@nvcancer.org.

3rd Annual John R. Murren Memorial Symposium: Advances in Genitourinary Cancer Treatment

Yale School of Medicine and Nevada Cancer Institute (NVC I) are pleased to announce that the 3rd Annual John R. Murren Memorial Symposium will be held at the Red Rock Resort & Spa Las Vegas, March 27 and 28, 2009. John Murren, M.D., was director of Medical Oncology Clinical Services at the Yale Cancer Center and among the founders of NVC I. In advancing his efforts, course directors, W. Kevin Kelly, M.D., Nicholas Vogelzang, M.D., and Giuseppe Pizzorno, Ph.D., Pharm.D., have gathered renowned national and international faculty who will provide evidence-based education to multidisciplinary clinicians involved in the screening, diagnosis and treatment of patients with genitourinary cancers.

The two-day symposium will focus on localized prostate cancer and treatment of bladder and renal cancers. Among the scheduled topics include: advances in radiotherapy;

updates on new surgical approaches including robotics; brachytherapy for prostate cancer; the future of Androgen deprivation therapy; the role of circulating tumor cells in the management of prostate cancer, Updates on Local Recurrent Bladder Cancer, Radiologic Imaging of Renal Cell Carcinoma; and Management of Isolated Renal Mass. Scheduled panel

and case study discussions will include treatment of localized prostate cancer; local and metastatic cases; bladder and kidney cancers.

Online registration available at cme.yale.edu. For more information about this symposium please contact the Yale School of Medicine Center for Continuing Medical Education at 203-785-4578

SAVE THE DATE:
March 27-28, 2009

On-line Registration:
www.cme.yale.edu

Information:
203-785-4578

CME

In the spirit of discovery and collaboration Nevada Cancer Institute is dedicated to the advancement of knowledge and education. Our multidisciplinary approach to medicine is an important part of our patient care philosophy. Nevada Cancer Institute generally hosts two CME activities each month. Among our continuing education program include Tumor Board Presentations and our Grand Rounds Lecture series.

Nevada Cancer Institute hosts monthly tumor board presentations and grand rounds lectures that address the current state of care for a particular cancer. These discussions include a presentation of interesting and/or difficult case studies. Nevada Cancer Institute and community physicians have the opportunity to discuss various aspects of these cases including diagnosis with pathology and radiology presentations as well as treatment plans and can also discuss other recommendations for treatment. Nevada Cancer Institute tumor boards also provide valuable medical education for all medical disciplines with the fundamental learning objective of understanding diagnosis, treatment, clinical trial options and outcomes for the specific malignancy discussed.

Upcoming Events:

January 9, **David Reisman, M.D., Ph.D.**
University of Michigan, Division of Hematology/Oncology

February 26, **Ronald DePinho, M.D.**,
Harvard Medical School

March 12, **James J. Rusthoven, M.D., MHS,**
FRCP, FACP will discuss Medical Ethics

Nevada Cancer Institute is accredited by the Nevada State Medical Association to provide continuing medical education to physicians. Nevada Cancer Institute designates educational activities for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity. The Nevada State Board of Nursing allows licensed nurses to apply CME Category 1 credit toward the renewal of their nursing license.

For additional information about Nevada Cancer Institute lectures, contact **Crystal Franzese**, Manager, Continuing Education Programs at (702) 822-5433.

Contact NVC I

LAS VEGAS: 702-822-5433 | One Breakthrough Way, Las Vegas, Nevada, 89135

SPARKS: 775-356-8800 | 1301 North McCarran Boulevard, Suite 101 Sparks, Nevada, 89431

ELKO: 775-738-4673 | 2596 Idaho Street, Elko, Nevada, 89801

FALLON: 775-423-7060 | 2125 West Williams Avenue, Fallon, Nevada 89406

To refer a patient call (702) 822-5111



Nevada Cancer Institute Registry Data

Nevada Cancer Institute's Registry gathers accurate, comprehensive and timely data on patients who are diagnosed and/or treated at the Institute. Information from the Cancer Registry can be used in research and epidemiologic studies of cancer to help understand the etiology of this disease. Nevada residents benefit from Cancer Registry data because research will lead to improved diagnostics and treatment strategies. Our researchers work with government cancer data researchers and population scientists to monitor cancer trends in Nevada.

Nevada Cancer Institute started to treat and/or consult with patients in April 2005. The following cancer information was gathered through August 2008.

There are 3,068 cases in NVCI's Cancer Registry. These are patients that have been newly diagnosed and/or treated or have sought out a second opinion for their malignant cancer. 56.3 percent of the patients are men and 43.7 percent are women. Below are the top 10 cancer sites seen at NVCI.

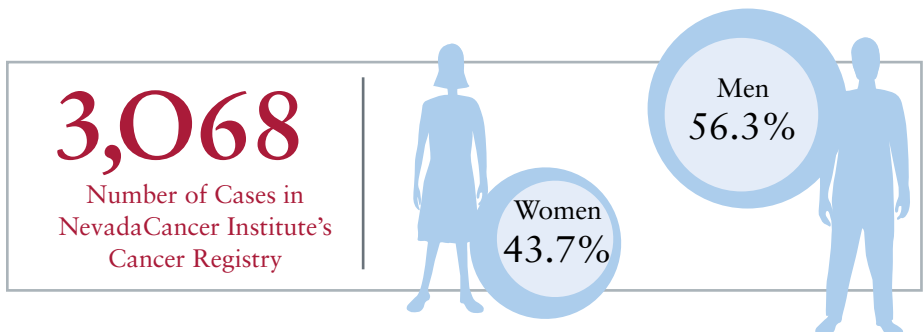
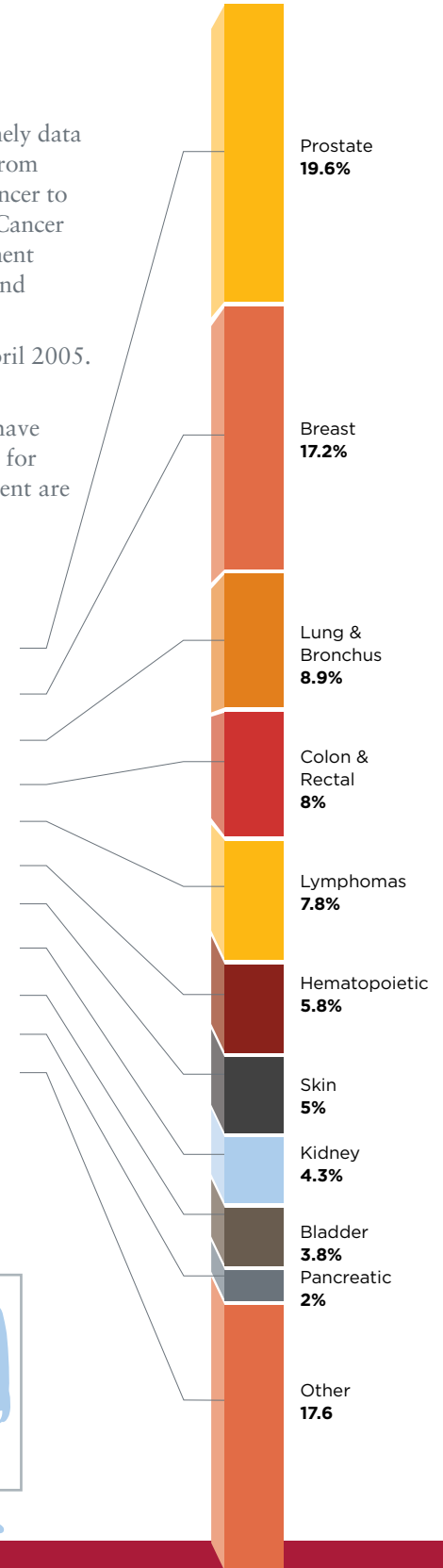
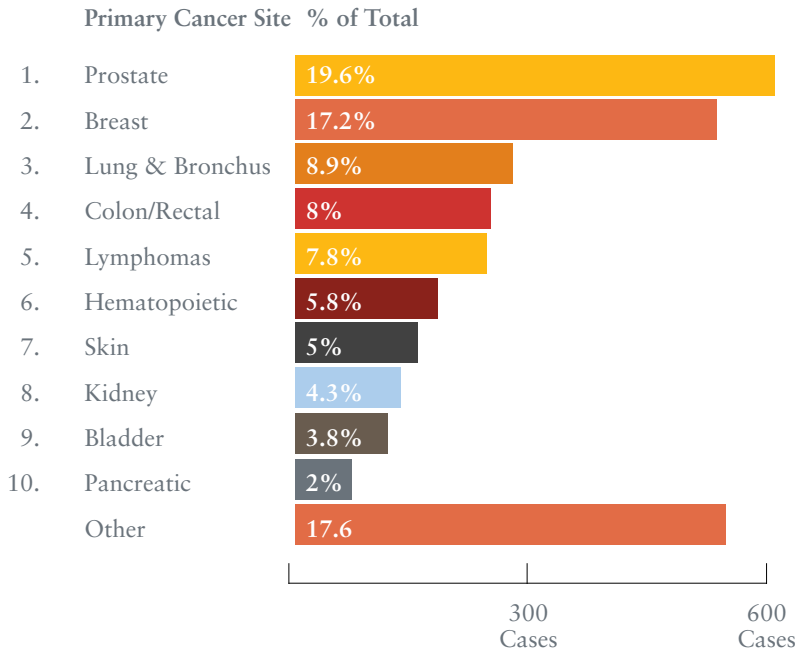




PHOTO: FRANCIS GEORGE

NVCI patient Teri Livengood recently celebrated her survivorship with a trip to Europe.

MY STORY: Teri Livengood

It was October 12, 2005, when I was informed that the five-centimeter mass on my chest X-ray was lung cancer; my mind immediately went to planning for my death. When my general practitioner referred me to Nevada Cancer Institute (NVCI), I reluctantly went, expecting confirmation of my belief that I was going to die. I also expected that they would offer some new drug—which I would equate with unnecessary torture—and that I would then politely refuse it, go home and prepare to die.

Entering NVCI was a warm and welcoming experience, and my first meeting with Dr. (Sunil) Sharma (chief of Gastrointestinal Oncology and of the Clinical Phase I Unit), began to change my attitude. He informed me that more testing had to be done to determine the type and stage of the cancer before appropriate treatment could be prescribed. He also promised to be completely honest with me. After the testing was completed, he recommended a Phase I clinical trial as the course of treatment.

Though frightened, I decided that for my family, I would do whatever Dr. Sharma recommended, including quitting smoking, for one year. If at that point I didn't see significant progress, treatment would be over. Chemotherapy reduced the tumor by about 59 percent. I was then placed in the care of Dr. Dave Pomerantz (director of Clinical Radiation Oncology) and received seven weeks of radiation, which reduced the tumor to one centimeter. A second round of radiation was recommended and completed in June 2007. Dr. Dave feels that the possibility for a cure is very good.

Cancer has given me a new appreciation for life. I took a wonderful trip to Europe in August, and I'm feeling good. I know that my survival is due to the care that I've received from the staff at NVCI in an environment of comfort, healing and safety. Together with my wonderful network of loving and supportive family and friends, they have brought me hope.



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