New Data Show Favorable Outcomes on Measures of Quality of Life and Toxicity for Prostate Radiosurgery Using Varian and Calypso Technology

Results of a phase II study summarized in presentation at the 2011 Annual Meeting of the American Society for Radiation Oncology (ASTRO)

MIAMI, Oct. 5, 2011 /PRNewswire/ -- Early results from a prospective Phase II trial presented today at the American Society of Radiation Oncology 53rd annual meeting show that patients with low-risk prostate cancer who were treated with radiosurgery using treatment technologies from Varian Medical Systems (NYSE: VAR) and Calypso Medical Systems had favorable health-related quality of life scores and minimal toxicities.

Patients in the study received stereotactic body radiotherapy (SBRT) delivered using Varian's Trilogy® system for image-guided radiotherapy, and Calypso's GPS for the Body® technology for the precise tracking of tumors during treatment. SBRT, which differs from traditional radiotherapy in that higher doses are given over a shorter number of treatments, is an emerging treatment for prostate cancer and a viable alternative, in some cases, to more invasive surgical procedures that require hospital stays and long recovery periods. Possible advantages of SBRT include fewer side effects and greater patient convenience (1).

"Preliminary results of this study add to the growing body of evidence reinforcing the benefit of SBRT for the management of localized prostate cancer," said Constantine Mantz, M.D., lead author and radiation oncologist at 21st Century Oncology in Ft. Myers, FL. "Minimizing common adverse effects such as sexual dysfunction and incontinence is very important, as they can significantly diminish quality of life among men undergoing treatment for prostate cancer."

According to Dr. Mantz, real-time tumor tracking is proving to be an important tool in reducing treatment margins during SBRT for prostate cancer, which is critical in limiting side effects. "Results from our Phase II trial show that real-time tumor tracking with SBRT for early stage prostate cancer has clinically significant benefits in decreasing acute toxicity, as well as improving quality of life and biochemical outcomes," he said. "The Calypso® System, which helps to enable physicians to deliver increased doses of radiation directly to the tumor while helping to spare the surrounding healthy organs from exposure, is fundamental to our overall approach of successfully treating prostate cancer."

The study examined a series of 80 patients that had received treatment since January 2007. Patients received five treatments, occurring on alternate days, each consisting of 8.0 Gray (a measure of radiation dose). Patients were asked to complete a quality of life questionnaire before and after treatment. Urinary and rectal toxicity were assessed during treatment and at defined follow-up points.

One month after treatment, men experienced a clinically significant decline in urinary irritation and obstruction compared to before treatment. Other measures, including urinary incontinence, bowel/rectal function, and sexual function did not worsen post-treatment.

After one year, no measure of toxicity increased compared to when treatment was started. Notably, rectal toxicity, a known side effect of older radiotherapy methods for prostate cancer, was uncommon. Only two patients reported mild rectal bleeding at 6 and 9 months, respectively, and in both cases the issue resolved without intervention. Tumor response was measured using PSA measurements, which fell rapidly over the first 24 months.

"Varian technology for delivering advanced forms of image-guided radiotherapy—including SBRT—are helping to advance the treatment of low-risk prostate cancer," said Chris Toth, senior director of marketing
For Varian's Oncology Systems business. "By combining Varian's accurate treatment delivery with the real-time tracking capabilities of the Calypso System, SBRT appears to help men effectively address their disease while potentially minimizing side effects."

Study Details

Researchers in the study highlighted at ASTRO treated 80 patients considered to have low-risk disease with SBRT utilizing the Varian Trilogy system for delivery of intensity modulated radiotherapy, and the Calypso System for real-time electromagnetic target tracking.

The Calypso System was used prior to each treatment session for target localization, and cone beam CT imaging using the Trilogy imager was used for verification of target setup and assessment of possible target deformation. The Calypso System was then used to provide real-time target tracking continuously during treatment delivery. A threshold of 2 mm was prescribed for all treatments, so that if the target moved more than 2 mm in any direction, treatment was paused or the patient's position was adjusted (2).

Eighty patients have completed protocol treatment since January 2007 and have been followed for greater than 18 months, and for a median of 36.2 months. Patient-reported quality of life was assessed before and after the completion of radiation therapy using a clinically validated questionnaire, the Expanded Prostate Cancer Index Composite (EPIC) that measures several different domains of the patient's health (3). EPIC scores were segregated into bowel/rectal, urinary irritation/obstruction, urinary incontinence and sexual functions. At 1 month, 42.8 percent, 16.3 percent and 14.2 percent of patients reported grades 1-2 urinary frequency, dysuria and obstruction, respectively. At 6 months, respective grade 1 urinary toxicity rates were 21.8 percent, 3.1 percent and 3.2 percent. Mean pre-treatment and 12-month and 36-month post-treatment values were 6.92, 1.03, and 0.2 ng/ml respectively for biochemical response measurements. The NCI CTCAE v3.0 was used to assess urinary and rectal toxicity during treatment and at defined follow up points.

Varian and Calypso recently announced that they have signed a definitive agreement under which Varian will acquire Calypso. For further details, refer to: Varian Medical Systems Signs Agreement to Acquire Calypso Medical Technologies; Acquisition Adds Products for Tracking Tumor Motion During Radiosurgery and Radiotherapy.

About Calypso Medical Technologies, Inc.

Calypso Medical is a privately held medical device company headquartered in Seattle. Its proprietary tumor localization system is designed for body-wide cancers commonly treated with radiation. Utilizing miniaturized, non-ionizing implanted devices called Beacon® electromagnetic transponders, the Calypso System continuously and accurately tracks the location of cancerous tumors for the improved precision and safe management of radiation for cancer treatment. The real-time position and motion information provided by the Calypso System offers objective reassurance that radiation treatment is delivered precisely to the prescribed target and not to surrounding healthy tissue, thereby improving safety and eliminating unnecessary radiation exposure to patients. The Calypso System was cleared by the U.S. Food & Drug Administration (FDA) for use in radiation therapy for the prostate and post-operative prostatic bed. Additional information can be found at www.calypsomedical.com.

About Varian Medical Systems

Varian Medical Systems, Inc., of Palo Alto, California, is the world's leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, and brachytherapy. The company supplies informatics software for managing comprehensive cancer clinics, radiotherapy centers and medical oncology practices. Varian is a premier supplier of tubes and digital
detectors for X-ray imaging in medical, scientific, and industrial applications and also supplies X-ray imaging products for cargo screening and industrial inspection. Varian Medical Systems employs approximately 5,700 people who are located at manufacturing sites in North America, Europe, and China and approximately 70 sales and support offices around the world. For more information, visit http://www.varian.com or follow us on Twitter.

Varian's Trilogy linear accelerators are indicated to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated. While clinical studies such as those highlighted here may support the effectiveness of Varian's technology when used for radiotherapy or radiosurgery, individual results may vary. There are no guarantees of outcome, and Varian's regulatory clearances do not incorporate improved quality of life claims.

The Calypso 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso System provides accurate, precise and continuous localization of a treatment isocenter by using two or more Beacon transponders. Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures. Permanent Beacon transponders are indicated for permanent implantation in the prostate and the peri-prostatic tissue (i.e., prostatic bed).

FOR INFORMATION CONTACT:
Varian Medical Systems For Calypso Medical
Meryl Ginsberg, 650.424.6444 Amy Cook, 925.552.7893
meryl.ginsberg@varian.com acook@calypsomedical.com


SOURCE Varian Medical Systems

http://investors.varian.com/index.php?s=31868&item=103379