Initial and Longer-Term Results Demonstrate Low Toxicity Rates with SAVI 5-Day Breast Cancer Treatment

The Associated Press

ALISO VIEJO, Calif.--(BUSINESS WIRE)--Apr 12, 2012-- New research findings on the SAVI(R) breast brachytherapy applicator showed favorable results for SAVI treatment of early-stage breast cancer, according to a scientific poster at the annual meeting of the American Society of Breast Disease (ASBD).

Examining initial and longer-term effects among a large group of 909 patients at 12 centers around the U.S., researchers found low rates of toxicities among SAVI patients.

"The results indicate SAVI breast brachytherapy has very low rates of side effects, which compare favorably to rates reported in studies of other forms of breast brachytherapy," said Jon Strasser, M.D., the lead researcher and a radiation oncologist at Helen F. Graham Cancer Center, Christiana Care Health System, in Newark, Del.

Dr. Strasser and colleagues looked at several potential side effects of SAVI brachytherapy, which is a form of radiation treatment called accelerated partial breast irradiation (APBI).

"Our findings help confirm that this is cutting-edge, very modern treatment for many forms of early-stage breast cancer," Dr. Strasser said. "Moreover, it is now available at cancer centers in many communities. Women don't need to travel to an academic medical center to receive this sophisticated therapy." The SAVI Collaborative Research Group, from which the data was drawn, was established to study clinical outcomes of APBI treatment with the SAVI device. The data represents the largest subset of patients who have been treated with the SAVI applicator.

In the 12-sitedata reported by Strasser, researchers found that rates of seroma, fat necrosis and telangiectasia - potential side effects of any form of APBI - were low among patients at one year and two years after SAVI therapy. Also, researchers noted at 6 weeks, there were very few acute toxicities, including low risk of infection, skin erythema or edema.

Rates of seroma (a collection of fluid at the site of the lumpectomy and radiation treatment) were 2.6% at one year among the 413 patients at that point after treatment. Rates of telangiectasia (visible dilated blood vessels near the surface of the skin) were 2.7%. Fat necrosis was observed in 1.7% of patients at one year.

"Good results such as these are among the reasons many women like this form of treatment," Dr. Strasser said. "They appreciate that it is an easy way to take care of

the radiation portion of their therapy in just five days. That means they can quickly resume their normal daily routines and know that they've received really good treatment." A separate set of data on SAVI therapy, also reported at the ASBD conference, came from Ben H. Han, M.D., and colleagues at South Florida Radiation Oncology, in Wellington, Fla. They reported on 75 SAVI patients and concluded that, with SAVI's ability to carefully control radiation dosages, the therapy allows for APBI treatment of more women, even when the treated area is close to healthy tissues.

SAVI delivers a shortened course of radiation therapy for early-stage breast cancer patients following lumpectomy surgery. It is the only single-entry breast brachytherapy device that allows physicians to sculpt radiation based on patient-specific anatomy, which increases the number of women who can benefit from APBI. Clinical studies show that by providing targeted radiation where it is needed most, SAVI decreases toxicity and lowers the risk of cosmetic side effects.

This radiation treatment is part of breast-conservation therapy, which includes lumpectomy- the surgical removal of the cancerous tissue within the breast plus tissue immediately around the tumor - followed by radiation. This approach is an alternative to mastectomy, which removes the entire breast and is often followed by breast reconstruction.

Radiation treatment after a lumpectomy has traditionally involved irradiation of the entire breast with an external beam. Besides the inconvenience of the six-week-long regimen, many women must travel some distance to receive external-beam radiation. That can put additional stress on their families, jobs, and financial resources.

About Cianna Medical, Inc.

Cianna Medical, Inc. is a medical device company focused on women's health and dedicated to the innovative treatment of early-stage breast cancer. The company manufactures and markets the SAVI breast brachytherapy applicator, for the delivery of radiation after lumpectomy surgery. The SAVI applicator allows precise sculpting of the radiation dose, and is designed to make the benefits of accelerated partial breast irradiation available to a greater number of women.

For more information, call (toll-free) 866-920-9444 or visit www.ciannamedical.com.

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