

Seno Medical Instruments, Inc. Launches Pivotal Study of New Functional Imaging Platform in Breast Cancer Diagnosis

SAN ANTONIO, TEXAS – November 25, 2013 – Seno Medical Instruments, Inc., the company pioneering opto-acoustic imaging as a tool to improve the diagnosis of cancer, announced today that the first 100 patients have been enrolled into its Pivotal Study of Imagio™, a new opto-acoustic imaging system that may help women with benign breast masses avoid negative, invasive biopsies.

Each year in the U.S. 1.7 million women undergo core needle or surgical breast biopsies after a suspicious mass is found through screening mammograms or self-exams and a series of diagnostic imaging tests are performed. However, four out of five of these biopsies reveal benign pathology.

Imagio combines traditional ultrasound with an imaging technology based on light in and sound out called “opto-acoustics.” The opto-acoustic images provide a unique blood map in and around suspicious breast masses. Unlike other imaging modalities, Imagio doesn’t expose patients to potentially harmful ionizing radiation (x-rays) or injectable contrast agents.

“Although breast cancer is one of the most prevalent causes of death in women, the tools used to diagnose this disease have certain limitations that can make the process intrusive, costly and potentially harmful to patients,” said Thomas Stavros, M.D., Medical Director, Seno Medical Instruments. “Breast biopsies, the current standard of care for diagnosing or ruling out cancer, are the most expensive part of the breast cancer diagnostic process. By providing a real-time blood map co-registered with ultrasound images, we believe that opto-acoustics can provide radiologists more information than ever before to help them confidently rule out cancer so that fewer women with benign lesions will have to undergo biopsies and the worry that can come from the process.”

Because cancerous tumors grow relatively quickly, they require significant amounts of blood and oxygen, so a network of blood vessels grows around cancerous masses. Imagio provides images of these networks and a map of oxygen-rich or oxygen-deprived blood. Radiologists believe that Imagio images depicting significant vascular structures and low oxygen levels are likely to indicate cancer.

The Imagio Pivotal Study will include 16 leading hospitals and imaging centers throughout the United States.

“Scanning the first 100 patients and starting the active enrollment phase is an important milestone for us in our mission to deliver a new standard in breast cancer diagnosis,” said Janet Campbell, CEO of Seno Medical Instruments. “We believe Imagio can offer a better diagnostic alternative for women who have suspicious breast masses, and can help physicians more confidently rule out cancer with a less invasive test. Based on conversations with some of the top minds in radiology, we are encouraged that this new modality could have a significant impact breast cancer diagnosis.”

The American Cancer Society estimates that there were more than 2.9 million women with a history of invasive breast cancer living in the U.S. in 2012, with 226,870 of them diagnosed during the year.