

New Data Presented at San Antonio Breast Cancer Symposium Confirms Correlation Between the Imagio® Opto-Acoustic Breast Imaging System and Histologic Grade of Breast Masses

Additional Data Validates Potential of Imagio® Opto-Acoustic Breast Imaging System to Reduce Negative Biopsies

NEWS PROVIDED BY Seno Medical Instruments, Inc. Dec 09, 2016, 07:00 ET SAN ANTONIO, Dec. 9, 2016 /PRNewswire/ — Seno Medical Instruments, Inc., the company pioneering the development of opto-acoustic (OA) technology as a new tool to improve the process of diagnosing breast cancer, today announced results from two analyses of the company's European MAESTRO post-market surveillance study. The two analyses were presented at the 2016 San Antonio Breast Cancer Symposium (SABCS) in San Antonio, Texas.

MAESTRO, a controlled, multi-center, observational, post-market surveillance and clinical follow-up study, was designed to assess the diagnostic value (specificity and sensitivity) of OA to conventional diagnostic ultrasound (CDU) in suspicious masses classified as BI-RADS 4a and 4b. Investigators first performed CDU to reach a diagnosis and decision to biopsy followed by an Imagio OA examination. Two hundred female subjects with undiagnosed suspicious masses enrolled in the study.

The first analysis evaluated the correlation between OA imaging results and histologic data of breast masses and found that there was a statistically significant correlation between the OA breast imaging results and those based on histopathologic analysis.

"These studies are an important step forward in the development of noninvasive breast imaging technology. Evaluation of the Imagio system significantly included an independent analysis of the patient's pathology, unparalleled in the pre-release development of any breast imaging technology," said F. Lee Tucker, MD, FCAP and pathologist for the PIONEER study in the U.S. "The findings indicate the Imagio system can provide an accurate and noninvasive differentiation of benign from cancerous breast masses and will be an important means of reducing the number of benign breast biopsies."

The histopathological examination revealed 146 benign masses and 67 malignant masses. For each mass, five pre-determined OA features, three internal features, and two external features were evaluated. The three internal scores (vessels, blush, and hemoglobin) and two external features (capsular boundary zone and peripheral boundary zone) were summed together and separately for testing relationships utilizing traditional histopathology measures. The OA feature scores statistically significantly differentiate between benign and malignant masses and appear to correlate to histologic grade.

The second study, an interim analysis from the MAESTRO study, presented OA imaging downclassification and upclassification data, which showed that the Imagio system improved physicians' ability to accurately classify breast masses as malignant or benign compared to using traditional ultrasound. Results from this study were first presented at the Annual Scientific Meeting of the

European Society of Breast Imaging (EUSOBI), the second largest conference in the world dedicated to breast cancer imaging, in September 2016 in Paris.

“The interim results from the MAESTRO study provide further evidence in a real-world setting, that the Imagio breast imaging system is a viable diagnostic tool to more accurately assess breast masses for malignancy compared to diagnostic ultrasound,” said Ruud Pijnappel MD, PhD, Professor Breast Radiology at UMC Utrecht, Netherlands and CEO of LRBC – Dutch Reference Centre for Screening. “We believe the final results of the MAESTRO study to be presented in 2017 will confirm these interim results.”

“Together, the two data presentations presented at the San Antonio Breast Cancer Symposium reinforce our belief that the Imagio breast imaging system will be an important tool to clinicians to evaluate suspicious masses while providing greater comfort to the patient,” said Tom Umbel, CEO of Seno Medical Instruments. “We will soon launch the Imagio system in Europe and look forward to the presenting the MAESTRO final results and the results of our pivotal trial in the US – PIONEER – in 2017.”

Seno Medical Instruments expects to announce the final results from the MAESTRO study in early 2017. Results from the company’s PIONEER study in the U.S. of more than 2,000 patients are expected to be announced in the second half of 2017. Seno Medical is targeting their PMA submission for the Imagio system to the U.S Food and Drug Administration in early 2017.

Seno’s Imagio system co-registers and fuses opto-acoustics, a technology based on “light in and sound out,” with diagnostic ultrasound – (OA/US). The opto-acoustic images provide a unique blood map in and around suspicious breast masses. Cancerous tumors grow relatively quickly and require significant amounts of blood and oxygen, so a network of blood vessels grows around cancerous masses. Imagio OA/US breast imaging system provides real-time images of these networks and a map of relative oxygen-rich or oxygen-depleted blood. Unlike other functional fusion technologies, Imagio uses no x-rays (ionizing radiation) or injectable contrast agents or radio-isotopes to obtain its information, thereby reducing the patient’s exposure to any potentially harmful aspects of imaging.

About Seno Medical Instruments, Inc.

Seno Medical Instruments, Inc. is a San Antonio, Texas-based medical imaging company committed to the development and commercialization of a new modality in cancer diagnosis: opto-acoustic imaging. Seno’s Imagio breast imaging system fuses opto-acoustic technology with ultrasound to generate functional and anatomical images of the breast. The opto-acoustic images provide a unique color map in and around suspicious breast masses while the ultrasound provides a traditional anatomic image. Through the appearance or absence of the two hallmark indicators of cancer – angiogenesis and deoxygenation – Seno believes that Imagio images will be a more effective tool to help radiologists confirm or rule out malignancy than current diagnostic imaging modalities – without exposing patients to potentially harmful ionizing radiation (x-rays) or contrast agents. Seno’s platform technology may also address other disease applications in organs other than the breast, as well as assessing other breast problems, such as early response to neoadjuvant chemotherapy or hormonal treatments of breast cancer. To learn more about Seno’s optoacoustic imaging technology and applications, visit <http://www.SenoMedical.com>

About the San Antonio Breast Cancer Symposium

The San Antonio Breast Cancer Symposium is an international symposium directed primarily towards academic and private physicians and researchers involved in breast cancer in medical, surgical, gynecologic, and radiation oncology, as well as other appropriate health care professionals. Approximately 7,500 attendees from more than 90 countries are expected to attend.

About Breast Cancer

According to the American Cancer Society, an estimated 246,660 new cases of invasive breast cancer, along with 61,000 new cases of non-invasive (in situ) breast cancer, will be diagnosed in U.S. women in 2016. Additionally, there are over 1.6 million biopsies performed annually and recent reported data noted an 81% “false positive” rate of biopsy procedures – the portion of biopsies that do not lead to breast cancer surgery. An estimated 40,450 women in the U.S. are expected to die in 2016 from breast cancer. Only lung cancer accounts for more cancer deaths in women.

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