Using a Real-Time Predictive Model to Interpret Images from Seno Medical Instruments Imagio Breast

SAN ANTONIO, Nov. 3, 2014 /PRNewswire/ -- Seno Medical Instruments, Inc., the company pioneering the development of opto-acoustic technology as a new tool to improve the process of diagnosing breast cancer, announced that the use of the Seno Imagio breast imaging system and the associated predictive model appear to have the potential to significantly improve the physicians' ability to accurately rule out breast cancer compared to traditional ultrasound alone.

"Diagnostic specificity, or the ability to accurately identify benign masses, remains disappointingly low for imaging methodologies optimized to identify all cancerous lesions with near 100% sensitivity," said A. Thomas Stavros, MD, Medical Director, Seno Medical Instruments. "We believe that by training Imagio readers with this real-time predictive model, they may be able to accurately reclassify benign breast lesions to a lower BI-RADS score so the patient can confidently avoid a biopsy on benign masses. If confirmed by Seno's prospective, multicenter PIONEER Pivotal Study of Imagio, the predictive model may improve the image reader's ability to accurately characterize solid breast masses as cancerous or benign and to spare women with benign lesions from the biopsy process beyond the standard-of-care today."

The predictive model is based on key opto-acoustic features of breast masses obtained by Imagio during a 79 subject pilot study. Seno completed active enrollment of 2,100 subjects in the U.S.-based PIONEER study in September. The results of the study will serve as the basis for the company's Premarket Approval Application (PMA) with the U.S. Food and Drug Administration (FDA).

Dr. Stavros presented results of the parallel reader study, which was designed to prospectively test the predictive model, at the 18th SIS World Congress on Breast Healthcare. The meeting, hosted by the American Society of Breast Disease and by the Senologic International Society, took place in Orlando, Fla. from October 16 to 19, 2014.

To develop the real-time predictive model, an expert radiologist blinded to histologic outcomes evaluated traditional diagnostic breast ultrasound and the 5 different Imagio opto-acoustic features of 79 masses (41 benign, 38 cancer) classified BI-RADS 4 prior to biopsy. Linear regression was used to model and predict the probability of malignancy, while logistic regression was used to model and to predict whether a mass was benign or malignant.

Three independent radiologist readers analyzed the gray scale ultrasound images and assigned BI-RADS categories and percentage risk of malignancy (POM) to each mass. They then scored the 5 individual Imagio opto-acoustic features and assigned BI-RADS categories and POM to each mass based upon OA without the predictive model applied. Finally, the readers repeated the Imagio OA feature analysis and assignment of BI-RADS category and POM with the aid of the predictive model. All three independent radiologists identified all of the cancerous lesions with Imagio images, generating 100% sensitivity across all readers, while one cancer was missed on gray scale ultrasound. With Imagio OA without the predictive model the IRs achieved 11%, 24%, and 25% better specificity than with conventional gray scale ultrasound. With the predictive model added, each independent radiologist was able to improve his/her ability to accurately classify a suspicious breast mass as benign by 28%, 36% and 38% achieving better specificity than with conventional gray scale ultrasound, respectively. Incremental improvements in specificity attributable to the predictive model (over subjective assignment) were 17%, 12%, and 13%.

"We are dedicated to improving the standard care for women after a suspicious mass is identified in one of their breasts. This new predictive model showed the increased potential of opto-acoustic images to help physicians confidently classify breast masses as benign, possibly eliminating the need for biopsies on certain breast masses," said CEO Janet Campbell. "We are completing the follow-up of all subjects who participated in our U.S. pivotal study and will submit these additional promising data sets to the FDA as part of Seno's PMA data package."

Imagio was designed to identify two functional hallmarks of a potential malignancy: the presence of abnormal blood vessels (angiogenesis) and the relative reduction in oxygen content of hemoglobin. The technology is non-invasive and does not require contrast agents or radio-isotopes, which are required for other modalities such as magnetic resonance imaging (MRI) or positron emission tomography (PET), nor does it use ionizing radiation (x-ray).

According to the American Cancer Society's estimates, 232,340 new cases of invasive breast cancer and an additional 64,640 cases of in situ breast cancer were diagnosed and approximately 39,620 women in the U.S. died from the disease during 2013. Only lung cancer accounts for more cancer deaths in women.

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 blood map 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 chemotherapy or hormonal treatments of breast cancer. To learn more about Seno Medical's opto-acoustic imaging technology and applications, visit www.SenoMedical.com

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