Seno Medical Instruments Investigator Speaking to Opto-Acoustic Breast Imaging as a Strong Predictor of Malignancy

Results Presented at the American Roentgen Ray Society (ARRS) Annual Meeting

San Antonio, May 10, 2017 – Seno Medical Instruments, Inc. (Seno Medical), the leader in new technology for breast cancer diagnosis, is using opto-acoustic (OA/US) imaging to differentiate benign from malignant masses. Seno Medical announced that its Imagio™ breast imaging system results correlate with the histopathological findings of benign and malignant breast masses. These data were highlighted during an oral presentation at the American Roentgen Ray Society (ARRS) Annual Meeting, which took place from May 1-5 in New Orleans.

The basis for this presentation is the institutional review board (IRB)-approved Phase III pilot study, which was designed to determine the histopathologic basis of OA/US breast imaging and investigate its ability to differentiate benign and malignant masses. A total of 92 patients with 94 solid or complex cystic and solid breast masses assessed as BI-RADS 3, 4 or 5 on conventional diagnostic ultrasound (CDU) were imaged with OA/US. For each mass, five pre-determined OA features – three internal features and two external features – were evaluated. The three internal features (internal vessels, blush and hemoglobin) and two external features (boundary zone vessels and peripheral zone vessels) were scored and correlated with benign and malignant histopathology.

Mean OA scores were higher for malignant masses compared to benign masses for all individual internal and external features, as well as for combined internal and external OA features. Statistical analysis showed that these differences were highly statistically significant. External features were more predictive of malignancy than internal features, with greater differences in their means and 99% confidence intervals between benign and malignant masses.

“These data reinforce previous findings suggesting that opto-acoustic diagnostic imaging may improve our ability to differentiate between benign and malignant breast masses. This could help us decrease the number of unnecessary breast biopsies performed for benign findings, reducing patient anxiety, discomfort and health care cost,” said Reni Butler, MD, principal study investigator and Assistant Professor of Radiology and Biomedical Imaging at Yale University School of Medicine. “Unlike previously investigated functional modalities, opto-acoustic imaging provides real-time anatomic and functional information without ionizing radiation or the need for IV contrast injection, making it a potentially safer and more convenient option for patients.”

“We are encouraged by these promising study results, further underscoring the clinical utility of the Imagio OA/US breast imaging system as an effective tool to aid in the assessment of breast masses,” said Tom Umbel, CEO of Seno Medical Instruments. “We are confident that OA/US imaging has the potential to address significant unmet needs in the characterization and diagnosis of breast lesions and look forward to announcing the results of PIONEER, our pivotal U.S. study of more than 2,000 patients, later this year.”

The Imagio™ OA/US breast imaging system was designed and is being studied to identify two functional hallmarks of cancer: the presence of abnormal blood vessels (tumor angiogenesis) and the relative reduction in oxygen content of blood that occurs in cancer compared to benign masses and normal tissues. The technology is the subject of a U.S. PMA filing with the FDA.

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 Medical's Imagio™ breast imaging system fuses opto-acoustic technology with ultrasound (OA/US) to generate fused real-time functional and anatomical images of the breast. The opto-acoustic images provide a unique blood map around breast masses while the ultrasound provides a traditional anatomic image. Through the appearance or absence of two hallmark indicators of cancer – angiogenesis and deoxygenation – Seno Medical believes that the Imagio OA/US breast imaging system 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. To learn more about Seno Medical's OA/US imaging technology and applications, visit www.SenoMedical.com.

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, were diagnosed in U.S. women in 2016. An estimated 40,450 women in the U.S. died in 2016 from breast cancer. Only lung cancer accounts for more cancer deaths in women.[1]

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[1] U.S. Breast Cancer Statistics | Breastcancer.org. (2016). Breastcancer.org. http://www.breastcancer.org/symptoms/understand_bc/statistics