Preliminary Data Show Seno Medical Instruments' Imagio™ Could Potentially Allow Doctors to Rule Out the Need for a Breast Biopsy

SAN ANTONIO, TEXAS – December 17, 2013 – Seno Medical Instruments, Inc., the company pioneering opto-acoustic imaging as a tool to improve the process of diagnosing breast cancer, today announced new statistical analysis of outcomes from a Feasibility Study of its investigational Imagio™ breast imaging device.

The analysis of data from the Feasibility Study, presented at the San Antonio Breast Cancer Symposium (SABCS) 2013 (Abstract P4-01-14) on December 13, 2013, suggests that information from Imagio may have the potential to achieve clinically-meaningful sensitivity and specificity for breast cancer beyond those achievable with traditional, standalone diagnostic ultrasound. If confirmed in a larger Pivotal Study – currently underway in the U.S. – Imagio may be a useful tool to help physicians rule out the need for a biopsy in patients with benign breast masses.

"These preliminary findings are encouraging and may support the biopsy-sparing potential of Imagio," said lead biostatistician Philip Lavin, PhD, FASA, FRAPS, who is a consultant to Seno Medical Instruments. "Surgical and core needle biopsies are considered the gold standard for breast cancer diagnosis, yet are the most expensive part of the diagnostic process. While existing breast imaging technologies are successful at positively identifying cancerous masses, it is very difficult to rule out cancer during the imaging phase and a large majority of biopsies come back negative for cancer."

This new statistical analysis of various features of benign and malignant lesions captured in the Imagio opto-acoustic images during the Feasibility Study also suggests that Imagio may have the potential to provide additional information that could help clinicians grade the aggressiveness of cancerous breast tumors during the imaging phase of a woman's diagnosis, if verified in the ongoing Pivotal Study.

Imagio combines an imaging technology based on light-in and sound-out called "opto-acoustics" with traditional ultrasound. 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.

For this study, proposed classification guidelines were developed to help identify features that differentiate images of benign and cancerous lesions, as well as the aggressiveness of the tumor. To develop the proposed classification guidelines, images of each tumor were assessed using three internal and two external features, which were scored on an ordinal scale from zero to five. The results were then summed to get a total internal score, total external score, and a total score. These results were then analyzed with five statistical classification methods.

"We are encouraged to see a high correlation between pathology results and classified features of masses captured in Imagio opto-acoustic images as part of this Feasibility Study," said Thomas Stavros, MD, FACR, FSRU, FRANZCR, Medical Director, Seno Medical Instruments. "Our ongoing Pivotal Study will hopefully provide evidence to confirm our hypothesis and this early data."

Each year in the U.S. 1.7 million women undergo core needle or surgical breast biopsies after a suspicious mass is found through breast imaging or self-exams. However, up to four out of five of these biopsies reveal benign pathology .

About San Antonio Breast Cancer Symposium (SABCS)

For thirty-six years, the Symposium's mission has been to provide state-of-the-art information on breast cancer research. From a one-day regional conference, the Symposium has grown to a five-day program attended by a broad international audience of academic and private researchers and physicians from over 90 countries. The Symposium aims to achieve a balance of clinical, translational, and basic research, providing a forum for interaction, communication, and education for a broad spectrum of researchers, health professionals, and those with a special interest in breast cancer.