

**New Interim Results Support Imagio® Opto-acoustic (OA) Breast Imaging System's  
Potential to Reduce Negative Biopsies**

***Company Plans to Deliver First Imagio® Opto-Acoustic (OA) Breast Imaging Systems  
to Select Markets in Europe in Early 2017***

SAN ANTONIO, Sept. 24, 2016 -- Seno Medical Instruments, Inc. (Seno), the company pioneering the development of opto-acoustic technology as a tool to improve the process of diagnosing breast cancer, announced today interim results from the company's multicenter, European MAESTRO post-market surveillance and clinical follow-up study. The results demonstrate the potential of its Imagio® opto-acoustic (OA) breast imaging system to provide physicians with vital information needed to determine whether or not a suspicious mass is cancerous, with the goal of reducing the rate of negative biopsies. The data were presented at a clinical symposium 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, on September 24, 2016 in Paris.

"The interim results from MAESTRO add to the growing body of clinical evidence showing that the Imagio opto-acoustic diagnostic tool increases physicians' confidence when differentiating and classifying malignant and benign breast tissue," said the study's principal investigator Ruud Pijnappel, MD, PhD, Radiologist, University Medical Center, Utrecht, NL, who presented the interim analysis. "The improved accuracy that is possible with this technology could help women avoid painful biopsy procedures that sometimes follow false-positive diagnoses."

There are over 1.6 million biopsies performed annually<sup>1</sup> 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.<sup>2</sup> Seno's Imagio breast imaging system, which received its CE Mark in 2014, has the potential to reduce negative biopsies by 43%. Seno Medical is targeting their PMA submission for the Imagio system to the U.S Food and Drug Administration by the end of 2016.

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 Opto-Acoustics 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 interim analysis of 78 subjects found that following the use of Imagio system, radiologists downgraded BI-RADS categories of the internal ultrasound control-classified BI-RADS 4a masses to BI-RADS 3 or 2 in 75% of cases, and BI-RADS 4b masses to either BI-RADS 3 or 2 in 37.5% of cases. The interim results also showed that Imagio OA also increased specificity to over 43%, with no significant loss in sensitivity.

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<sup>1</sup> J Womens Health, September 2014, Vol. 23:S1,

<sup>2</sup> An Actuarial Analysis of Breast Cancer Screening and Follow-on Diagnostics in a Commercially Insured Population.(2014).Milliman, Inc., NY. <http://www.milliman.com/uploadedFiles/insight/2014/actuarial-analysis-breast-cancer-screening.pdf>

Importantly, clinicians were able to reduce the rate of false-positive diagnoses by 20% for the last 48 subjects evaluated in the study.

"The interim results of the MAESTRO study are promising and could help physicians reliably and safely assess suspicious masses to deliver optimal treatment for each patient," said Tom Umbel, CEO of Seno Medical Instruments. "We look forward to the delivery of the first Imagio OA/US systems in the Netherlands, UK and Germany early next year."

Final results from the MAESTRO study are expected to be announced in early 2017. Enrollment for a U.S. trial of more than 2,000 patients has been completed and results will be announced in the latter half of 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 opto-acoustic imaging technology and applications, visit [www.SenoMedical.com](http://www.SenoMedical.com)

#### **About EUSOBI Annual Scientific Meeting**

The EUSOBI Annual Scientific Meeting consists of plenary lectures, workshops, symposia, poster sessions and technical exhibitions. The conference attracted renowned international speakers who shared their latest information and perspectives on emerging technologies in the breast cancer imaging space.

#### **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. 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.<sup>3</sup>

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<sup>3</sup> U.S. Breast Cancer Statistics | Breastcancer.org. (2016). Breastcancer.org.  
[http://www.breastcancer.org/symptoms/understand\\_bc/statistics](http://www.breastcancer.org/symptoms/understand_bc/statistics)