

## Seno Medical Instruments Announces New Data Demonstrating That Imagio™ Opto-Acoustic Breast Imaging System Delivers Critical Diagnostic and Prognostic Information About Tumor Subtypes

- *Prospective clinical study presented at the San Antonio Breast Cancer Symposium suggests Imagio findings may help clinicians tailor patient treatment regimens -*
- *Functional Imaging provides important information about the growth and location of blood vessels around breast masses as compared to anatomical imaging-*

SAN ANTONIO, December 8, 2017 – Seno Medical Instruments, Inc. (Seno Medical), the leader in new technology for breast cancer diagnosis using opto-acoustic (OA/US) imaging to differentiate benign from malignant masses, reported clinical data from their clinical study demonstrating that its Imagio™ breast imaging system achieved significant differentiation among prognostic subtypes of breast cancer (PSBC). These prognostic subtypes provide important information about the genes that each patient's cancer expresses. The data are being presented today at 5:00 p.m. during a poster presentation [#P5-02-04] at the San Antonio Breast Cancer Symposium taking place December 5 – 9.

"Confirming a diagnosis of breast cancer is just the first step in understanding the pathology of a patient's tumor," said study presenter Stephen Grobmyer, M.D., Director, Breast Surgical Oncology, Cleveland Clinic. "Determining a patient's prognostic subtype of breast cancer is essential for understanding how tumors will respond to specific therapies and selecting a treatment regimen that offers the patient the best chance of a positive outcome. The findings that OA/US may differentiate among several breast cancer subtypes suggest that this novel imaging methodology could potentially provide a non-invasive alternative to biopsy without sacrificing information about the molecular pathology of the tumor. This could be an important advance for women with breast cancer."

The prospective, multi-center study was conducted at 16 centers in the United States. A total of 1,808 breast masses in 1,739 subjects assessed as BI-RADS (Breast Imaging and Reporting Data System, or BR) category 3, 4 or 5 were imaged with OA/US, resulting in the identification of 678 malignant lesions. Eight blinded readers scored these 678 lesions based on three internal features of the tumor and two external features of the tumor boundary and surrounding tissue. An experienced central breast pathologist who was blinded to the OA/US assessment confirmed the pathologic diagnoses. Biopsy specimens were obtained and assessed for the expression of four genes that comprise the PSBC: estrogen receptor (ER), progesterone receptor (PR), HER2-*neu* (HER2) and Ki-67. The PSBCs are defined as follows:

- Luminal A (LUM-A): ER/PR (+) and Ki-67 and HER2 (-). These tumors are often low grade, with slow tumor growth and are associated with the most positive prognosis.
- Luminal B (LUM-B): ER (+), PR (+/-), Ki-67 (+) and HER2 (+/-). These tumors are also low grade but grow more quickly than LUM-A.
- Triple-negative breast cancer (TNBC): ER/PR (-), Ki-67 (+/-) and HER2 (-). These tumors are aggressive and typically associated with poor prognosis.
- HER2-enriched (HER2): ER/PR (-), Ki-67 (+/-) and HER2 (+). These tumors tend to grow quickly but are responsive to anti-HER2 targeted therapies.

Tumors not meeting the definition of any of these categories were deemed unclassified.

Key findings from the study include:

- There was a significant difference in the sum of the three internal OA/US features between LUM-A and TNBC subtypes ( $p = 0.0256$ ) and borderline significance between LUM-A and LUM-B ( $p = 0.0831$ ) and LUM-A and HER2 ( $p = 0.0707$ ).
- There was a significant difference in the sum of the two external OA/US features between LUM-A and TNBC subtypes ( $p = 0.0001$ ) and LUM-B and TNBC subtypes ( $p = 0.0020$ ) and borderline significance between LUM-A and HER2 ( $p = 0.0617$ ).
- TNBC tumors showed mainly internal findings consisting of polymorphic intensely deoxygenated vessels.
- LUM-A tumors showed a paucity of internal findings and abundant external findings consisting of short perpendicularly oriented tumor vessels in the boundary zone (BZ whiskers), partial BZ deoxygenated blush, and peripheral radiating deoxygenated vessels.

"The results of this study underscore the clinical benefits that can be achieved with Imagio's functional imaging technology," said Tom Umbel, CEO of Seno Medical Instruments. "Unlike anatomical imaging techniques, such as mammography or conventional ultrasound, functional imaging provides important information about the growth and location of blood vessels in and around breast masses. These findings show that not only does this functional imaging data allow for more accurate diagnosis of breast cancer, it also correlates with existing prognostic breast cancer subtypes. This data may suggest that OA/US has the potential to provide physicians with a powerful tool for gaining insight into the molecular pathology of each patient's tumor without the need for invasive biopsy procedures. Seno Medical is committed to improving the care and outcomes of women with breast cancer through improved non-invasive diagnostic approaches."

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 and does have European CE Mark.

#### **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 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](http://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, 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>1</sup>

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<sup>1</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)