



## PRESS RELEASE

### **SuperSonic Imagine Announces Completion of Key Milestone in Largest ShearWave™ Elastography Breast Cancer Study *Study in China to Confirm the Benefits of ShearWave Elastography in Diagnosing Breast Cancer in an Asian Population***

**Aix-en-Provence, France, November 10, 2015** - SuperSonic Imagine (Euronext: SSI, FR0010526814), a company specializing in ultrasound medical imaging, today announced the enrollment completion of over 2270 patients, a key milestone in its study to evaluate the ability of ShearWave™ Elastography (SWE™) ultrasound technology to help better diagnose breast lesions in China. The diagnosis of breast cancer in Asian women is particularly challenging as they often have dense breast tissue.

This prospective, multi-center study, led by Prof. Cai CHANG from Fudan University Shanghai and Prof. AnHua LI from Sun Yat-Sen University Cancer Center, has been conducted in 22 locations across China, including renowned hospitals in Shanghai, Beijing, Guangzhou, Chengdu, Shenyang, Harbin, Xi'an, Zhengzhou, Fuzhou, and Nanjing. With both enrollment and assessment (SWE ultrasound examinations) phases now complete for all patients, the next step is to analyze the benefit of combining SWE evaluation of individual breast lesions to their BI-RADS<sup>®(1)</sup> classification. This will enable quantification of improvements in sensitivity and specificity of diagnosis resulting from the SWE ultrasound characterization. The BI-RADS is a classification system developed by the American College of Radiology that is used by radiologists to standardize and assist in reporting the probability of malignancy of a breast lesion.

This is the largest study to date of ShearWave Elastography for breast cancer diagnosis and aims at confirming the clinical benefits of SuperSonic Imagine's SWE technology to increase accuracy of cancer risk assessment with ultrasound. A previous 2011 study involving 1,800 patients of Western ethnicities, demonstrated that ShearWave Elastography when combined with conventional ultrasound criteria, was shown to significantly reduce the number of false positive cases and therefore improve the specificity<sup>(3)</sup> of diagnosis of mammary lesions<sup>(2) (3)</sup>. This has also been corroborated by several individual studies<sup>(4)</sup> in which the characterization of "probably benign and low suspicion" breast lesions has been significantly improved by SWE. Since then, the elastography criterion has been incorporated into the BI-RADS classification.

In addition to confirming the benefits of ShearWave Elastography across a broad population, the primary objective of the current study is to determine the clinical benefits of this technology on an ethnic group that is distinct from the Caucasian population, given that Asian women tend to have denser breast tissue. According to the American Cancer Society, Asian countries are burdened with a significant portion of the world's breast cancer incidence and mortality, accounting for 39% of new cases and 44% of deaths<sup>(5)</sup>. This high mortality rate among Asian women can be partially attributed to delayed or under-diagnosis arising out of the inability of mammography to detect suspicious lesions in dense breast tissue typically seen in the Asian population. SuperSonic Imagine's ShearWave Elastography technology displays a color-coded map of tissue elasticity in conjunction with a high quality two-dimensional ultrasound image, providing physicians a complete and accurate stiffness evaluation easily and quickly. Tissue stiffness is used by physicians to better characterize lesions and therefore help identify potentially malignant or other diseased tissue.

*“This study is instrumental in expanding SuperSonic Imagine’s global presence, as China is the second largest ultrasound market worldwide. China is projected to have nearly 2.5 million breast cancer cases by 2021 and we are focused on utilizing our innovative technology to help improve breast cancer diagnosis for women globally”* indicated Tom Egelund, Chief Executive Officer of Supersonic Imagine.

*“I am excited to be part of this ground breaking study as I believe SuperSonic Imagine’s ShearWave Elastography helps improve ultrasound imaging for breast cancer diagnosis in Asian women who often have dense breast tissue. With its ability to provide accurate tissue stiffness information with high diagnostic capabilities, their SWE technology has the potential to revolutionize breast cancer diagnosis among women in China”,* said Professor AnHua Li.

(1) **BI-RADS®**: Breast Imaging Reporting and Data System by the American College of Radiology  
Classification system used by radiologists, recommended for breast cancer screening, helping doctors to take appropriate action based on a classification system from AC1 to AC5 according to the probability of malignancy.

(2) **Shear-wave Elastography Improves the Specificity of Breast US: The BE1 Multinational Study of 939 Masses.** Berg *et al.* Radiology. 2012 Feb;262(2):435-49.

(3) Definitions:

- Specificity = ability to detect benign lesions
- Sensitivity = ability to detect malignant lesions
- Negative predictive value = reliability of the benign test
- Precision = percentage of correctly classified lesions

(4) References available on request.

(5) American Cancer Society, Global Facts and Figures 3<sup>rd</sup> addition, 2012 data

### About SuperSonic Imagine

Founded in 2005 and based in Aix-en-Provence (France), SuperSonic Imagine is a company specializing in medical imaging. The company designs, develops and markets a revolutionary ultrasound system, Aixplorer®, with an UltraFast™ platform that can acquire images 200 times faster than conventional ultrasound systems. Aixplorer® is the only system that can image two types of waves: ultrasound waves ensure excellent image quality and shear waves, which allow physicians to visualize and analyze the stiffness of tissue in a real-time, reliable, reproducible and non-invasive manner. This innovation, ShearWave™ Elastography, significantly improves the detection and characterization of numerous pathologies in several applications including breast, thyroid, liver and prostate. SuperSonic Imagine has been granted regulatory clearances for the commercialization of Aixplorer® in the main global markets. Over the past years, SuperSonic Imagine enjoyed the backing of several prestigious investors, among which Auriga Partners, Edmond de Rothschild Investment Partners, Bpifrance, Omnes Capital and NBGI.

For more information about SuperSonic Imagine, please go to [www.supersonicimagine.com](http://www.supersonicimagine.com)

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