

SuperSonic Imagine launches clinical trial in China to confirm the benefits of its technology on dense breast tissue, specifically targeting the Asian market

Aix-en-Provence, France, September 30rd 2014 - SuperSonic Imagine (Euronext: SSI, FR0010526814), a company specializing in ultrasound medical imaging which markets a new-generation ultrasound system, the Aixplorer[®], is pleased to announce the launch of a multicentric clinical trial. The aim of the trial is to determine how ShearWave[™] Elastography can contribute to the diagnosis of breast lesions in a population of Asian patients.

The initiative is part of the company's clinical strategy and aims at validating the clinical benefits of its technology. A previous study in 2011 involving 1,800 patients demonstrated that ShearWave[™] Elastography, combined with conventional ultrasound criteria, provided better diagnosis of mammary lesions⁽¹⁾ by significantly improving the specificity⁽²⁾ of the examination. Since then, the elastography criterion has been incorporated into the BI-RADS^{®(3)} classification by the American College of Radiology, and other academic societies have published recommendations of practice that unanimously acknowledge the results of the initial trial.

The trial currently underway in China will recruit approximately 2,000 patients. In addition to confirming the benefits of ShearWave[™] Elastography on a broad population, the primary objective is to determine the clinical benefits of this technology on a specific group which differs from the Caucasian population, given that Asian women tend to have denser breast tissue. The direction of the trial promoted by SuperSonic Imagine, has been entrusted to Professor Chang (Shanghai) and Professor Li (Guangzhou). Professors Chang and Li will be responsible for controlling the data collected from the 20 locations, which include the finest hospitals in Shanghai, Guangzhou, Beijing, Harbin, Xi'an, Chengdu, and Taiyuan.

"In China, the first-line method for breast cancer exploration is ultrasound, which is particularly well suited to dense breast tissue" explains Robin Le, Vice President of SuperSonic Imagine China.

"Given the strategic importance of the Chinese market, which is expected to represent a quarter of the worldwide ultrasound market by 2020, the trial will allow SuperSonic Imagine to position its technology with the same scientific rigor on which its reputation is built amongst academic societies" explains Claude Cohen-Bacrie, Co-founder and Scientific Director of SuperSonic Imagine.

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

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⁽¹⁾ **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.

⁽²⁾ 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

⁽³⁾ **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 ACR 1 to ACR 5 according to the probability of malignancy.

⁽⁴⁾ **Practice guideline for the performance of breast ultrasound elastography.** Lee *et al.* Ultrasonography. 2014 Jan;33(1):3-10.