ShearWave™ Elastography Acknowledged by Radiologists for Significantly Improving Diagnostic Performance of Ultrasound

The Associated Press

AIX EN PROVENCE, France--(BUSINESS WIRE)--Nov 26, 2012--With more than 50 studies published in peer reviewed medical journals confirming the clinical benefits of ShearWave Elastography, physicians continue to be inspired by this technology. The first clinical publications, based on breast imaging, greatly contributed to Aixplorer's reputation. Since then, other studies have evaluated the added value of ShearWave Elastography for diseases including prostate cancer, liver fibrosis, thyroid nodules and musculoskeletal disorders. The results of these studies have confirmed that ShearWave Elastography significantly improves the diagnostic performance of ultrasound.

"We are pleased that the medical community has recognized the clinical benefits of ShearWave Elastography in these applications," said Claude Cohen-Bacrie, co-founder, Executive Vice President and CTO of SuperSonic Imagine . "Moreover the FDA recently cleared Aixplorer's ShearWave Elastography to include a meters per second adjustable numerical scale that measures shear wave velocity. This clearance is the result of the acknowledgement by the FDA of the accuracy and precision of ShearWave Elastography. This meters per second scale allows the user to fine tune their SWE™ imaging to better visualize the differences in tissue stiffness." Aixplorer's major areas of clinical application: Thyroid nodules Since 2009 ShearWave Elastography has been an important diagnostic imaging tool for the examination of thyroid nodules. It has been the subject of several clinical studies worldwide, of which four important published studies demonstrated that ShearWave Elastography is a highly specific test that improves the positive predictive value of an ultrasound exam and help guiding FNAs performed on multi-nodular goiters.

Key published studies include: Dr Kunwar Bhatia, Hong Kong, ShearWave Elastography of thyroid nodules in routine clinical practice: preliminary observations and utility for detecting malignancy (European Radiology, 2012) Dr Rafal Slapa, Warsaw, Poland, ShearWave Elastography May Add a New Dimension to Ultrasound Evaluation of Thyroid Nodules: Case Series with Comparative Evaluation (Journal of Thyroid Research, 2012). Dr Sebag, Marseille, France, ShearWave Elastography: A New Ultrasound Imaging Mode for the Differential Diagnosis of Benign and Malignant Thyroid Nodules (J Clin Endocrinol Metab, December 2010) Dr Veyrieres JB, Toulon, Marseille, France, A threshold value in ShearWave Elastography to rule out malignant thyroid nodules: A reality? (European Journal of Radiology, 2012) Prostate Cancer Published clinical studies have also demonstrated that ShearWave Elastography imaging could significantly increase the positive biopsy rate and is an important tool for prostate cancer detection. Until now, the diagnosis of prostate cancer was based on 12-18 random biopsies. The ShearWave Elastography map displays tissue stiffness in real-time, helping physicians to depict regions of interest

for biopsy and potentially limit the number of biopsy samples. As ShearWave Elastography is real-time, its imaging could also be useful in guiding interventions such as radiofrequency ablation of tumors. Because it is reproducible, SWE could be used for follow-up to visualize the of neo-adjuvant treatments.

Key published studies include: Dr Richard Barr, Youngstown, OH, USA, ShearWave Ultrasound Elastography of the Prostate Ultrasound Quarterly, March 2012. Liver Fibrosis While conventional ultrasound provides morphological information, ShearWave Elastography imaging gives complementary information. The physician can easily adjust the numerical scale in meters per second (in USA) or in kilopascals (out of USA) to image the liver at various fibrosis stages and map the stiffness throughout the entire region of interest in real-time. The technology has been shown to have high sensitivity and specificity on hepatitis C patient and to be particularly effective in imaging difficult cases such as patients with ascites.

Key published studies include: Dr Giovanna Ferraioli, University of Pavia, Italy: Reproducibility of real-time ShearWave Elastography in the evaluation of liver, European Journal of Radiology (2012) Accuracy of real-time ShearWave Elastography for assessing liver fibrosis in chronic hepatitis C: A pilot study, 2012. Muscle Activity Monitoring To date, studies have focused on the physiological characteristics of muscles and tendons. ShearWave Elastography can assist in the characterization of tissue and injuries, as well as the monitoring of post-surgery and rehabilitation.

Key published studies include: , and : Analysis of muscle solicitation via elastography technique "supersonic shear imaging” Journal of Biomechanics, 2012. Aixplorer’s Expanding Applications: Abdominal, Gynecology, Pediatrics and Vascular Aixplorer’s expanding capabilities and applications allow the visualization of organs such as liver, kidneys, gallbladder, pancreas, bladder, spleen and uterus in order to detect, diagnose and monitor lesions, transplants and/or diseases.

The Aixplorer ultrasound system is also particularly well suitable for routine pediatric radiology and covers all pediatric applications. The UltraFast™ platform and the wide range of transducers help the physician to adapt to the constraint of these patients and overcome the technical constraints of Pediatrics (patient movement, apnea not possible, small anatomical structures). The B-Mode images are clinically detailed and the SWE map displays tissue stiffness in real-time. UltraFast Doppler is very convenient for pediatric examinations as the acquisition is very fast and the analysis can be done at a later time, without the patient present.

Aixplorer’s Second Imaging Advancement: UltraFast Doppler: 3 Seconds to acquire Color and Spectral Doppler Information Launched in 2011, UltraFast Doppler operates on Aixplorer’s UltraFast imaging platform, and is the only system to unite Color Flow Imaging with Pulsed Wave Doppler. The result is never-seen-before ultra-high frame rate Color Flow clips that are up to ten times faster than conventional Color Doppler. The same technology also acquires fully quantifiable Doppler data throughout the Color box, enabling the generation of post-processed Pulsed Wave Doppler spectra from multiple locations in the same image. The result is a complete flow analysis in a few seconds that is quick and accurate.

SuperSonic Imagine is exhibiting at RSNA congress, November 25th-30th Booth #9136, Hall B, McCormick Place, Chicago.

About SuperSonic Imagine (www.supersonicimagine.com) Founded in 2005 and based in Aix-en-Provence (France), SuperSonic Imagine is an innovative, international company specializing in ultrasound medical imaging. The company designs, develops, and markets a revolutionary ultrasound system, Aixplorer®, with a unique ultrasound imaging technology, called MultiWave™ Technology. This technology allows Aixplorer® to be the only ultrasound system that images two types of waves to better characterize tissue; an ultrasound wave to ensure impeccable image quality and a shear wave, ShearWave™ Elastography, to compute and display true tissue stiffness in real time by acquiring images nearly 200 times faster than conventional systems.

In 2009, SuperSonic Imagine was granted 510(k) clearance by the Food and Drug Administration in the United States and CE mark in Europe for the marketing of Aixplorer®.

Distribution agreements have been signed with prestigious companies such as Hologic (Nasdaq : HOLX) for the breast market in the U.S.A. and Canon (NYSE : CAJ) for Japan. SuperSonic Imagine’s distribution network has now more than 30 partners worldwide.

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