

SuperSonic Imagine Announces Clinical Data From Its Retrospective Multicenter Trial Evaluating ShearWave™ Elastography For The Non-invasive Staging Of Patients With Chronic Liver Disease

Aix-en-Provence, France, April 28, 2015 - SuperSonic Imagine (Euronext: SSI, FR0010526814) whose ShearWave Elastography™ (SWE™) and Ultrafast™ Doppler technologies have revolutionized the ultrasound imaging industry, today announced results from a large retrospective multicenter trial¹ of patients with chronic liver disease. These results were formally presented at the 50th Annual Meeting of the European Association for the Study of the Liver (EASL) by Professor Eva Herrmann of University Hospital Frankfurt Germany, statistician expert of the trial.

To date, over 40 peer-reviewed publications based on single center investigator-initiated trials have demonstrated the reliability and effectiveness of SWE™ in staging patients with chronic liver disease. This presentation at EASL showed for the first time results on a much larger scale (1340 patients) from a global multicenter retrospective meta-analysis. It confirmed the accuracy of SWE™ as a non-invasive alternative to biopsy for staging liver fibrosis/chronic liver disease.

Clinical data from 1340 patients with SWE™ measurements and liver biopsy were collected from 13 sites and retrospectively analyzed as a part of this analysis. This patient population was comprised of chronic hepatitis C (HCV, n=470), chronic hepatitis B (HBV, n=420), non-alcoholic fatty liver disease (NAFLD, n=172) or other liver diseases (n=278). 40.8% of the patients were found to have minimal or no fibrosis (\leq F1), 19.3% had significant fibrosis (\geq F2), 14.0% had severe fibrosis (\geq F3) and 26.0% had cirrhosis (F4).

Liver elasticity measurements were found to be well correlated with the fibrosis grade. SWE™ demonstrated robust sensitivity and specificity across all forms of liver disease. The primary endpoint of this trial was the overall performance of SWE™ measured as the area-under-the-receiver-operating-characteristic (ROC) curves (AUROC), using liver biopsy as the reference. AUROC is an indicator of the diagnostic performance of a clinical test to differentiate between patients with and without a disease: the test becomes closer to perfection as the score approaches 100%. Table 1 summarizes this performance:

Fibrosis Stage	All patients	HCV	HBV	NAFLD
≤ 1 vs. ≥ 2	86%	86%	92%	86%
≤ 2 vs. ≥ 3	91%	93%	94%	92%
≤ 3 vs. 4	95%	96%	97%	96%

This analysis demonstrated the remarkable ability of SWE™ to determine liver disease severity in a broad range of patients. Specifically, the results revealed the ability to accurately evaluate liver disease caused by hepatitis C, hepatitis B and non-alcoholic fatty liver disease including NASH (non-alcoholic steatohepatitis).

SWE™ is an easy-to-use, non-invasive exam that provides real time, color coded maps with quantitative measurements of liver stiffness that help assess chronic liver disease. As a general rule, liver stiffness increases with the severity of liver fibrosis, making it an important parameter to help physicians determine disease stage. Liver biopsy has traditionally been considered the gold standard for staging liver fibrosis but this invasive method has major drawbacks, including significant incidence of morbidity, procedure and hospitalization costs, and clinical shortcomings as fibrosis is underestimated in 10-30% of cases^{2,4}.

The accuracy of SWE™ combined with its procedural convenience has the potential to significantly reduce the number of liver biopsies used for the staging of fibrosis and assessment of cirrhosis. Such a paradigm shift will not only save time and hospital costs but also reduce morbidity and improve patients' quality of life. This technique may also play a significant role in monitoring antiviral therapies used to address health concerns such as hepatitis C.

Jacques Souquet, Ph.D., SuperSonic Imagine's Founder, Executive Vice President and Chief Strategic and Innovation Officer commented *"this meta-analysis is a seminal body of work for the company because it corroborates with all previous single center trials to reconfirm the excellent diagnostic performance of SuperSonic Imagine's ShearWave Elastography (SWE™) for the non-invasive staging of liver disease"*.

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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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