SuperSonic Imagine Announces the Completion of Patient Enrollment for Pivotal Liver Fibrosis Clinical Study in China

Study to evaluate the performance of SuperSonic Imagine's ShearWave[TM] Elastography for the non-invasive assessment of liver fibrosis severity in patients suffering from chronic Hepatitis B infection

Aix-en-Provence, France, June 23rd, 2016 – SuperSonic Imagine (Euronext: SSI, FR0010526814), the highly innovative ultrasound company, announced completion of enrollment for a large prospective multicenter liver study in China. The study aims at evaluating the performance of SuperSonic Imagine's real-time ShearWave Elastography (SWE™) for the non-invasive assessment of liver fibrosis in Chinese patients with chronic Hepatitis B infection.

This study led by Prof. Ping Liang from the People's Liberation Army Hospital (301) in Beijing, has been conducted in 14 locations across China. All of the 400 Hepatitis B patients recruited for the study had an ultrasound exam, including SWE, to measure liver stiffness and guide liver biopsy, as well as a blood test analysis. As the enrollment and examination are now complete, the next step is to analyze the outcome of these exams and evaluate the correlation between SWE measurements and liver fibrosis, and ultimately assess the diagnostic performance of SWE.

"We are committed to improving the lives of patients with liver fibrosis as a result of Hepatitis B infection and are pleased to have completed enrollment in this key study," said Jacques Souquet, SuperSonic Imagine's Founder and Chief Innovation Officer. "Liver disease is a major health problem in China that affects over 300 million people[1]. Our ShearWave Elastography exam offers clinicians a non-invasive option that has demonstrated its value to help with the assessment of liver disease[2-6] and clinical management of patients in several clinical publications[7-11].This prospective multicenter study in China will be a major step forward in the confirmation of this clinical value."

ShearWave Elastography is a non-invasive exam that provides a quantitative color coded map to visualize and quantify tissue stiffness during an examination. Liver stiffness increases with the severity of liver fibrosis, making it a key parameter for physicians to assess the severity of fibrosis. Over 70 international publications have demonstrated the reliability and effectiveness of SuperSonic Imagine's SWE in this area.

"Clinicians require the most advanced tools available to be able to better manage and treat liver diseases, as China accounts for 51% of the deaths from liver cancer alone worldwide[1]," said the study's Principal Investigator Prof. Liang. "This study will provide new insights on ultrasound liver elasticity measurement and will help in evaluating the severity of intermediate stages of chronic liver fibrosis, which is key for effective treatment and management."

(1) The Global Burden of Liver Disease: The Major Impact of China. Fu-Sheng Wang et al. HEPATOLOGY, December 2014
(2) Quantitative Elastography of Liver Fibrosis and Spleen Stiffness in Chronic Hepatitis B Carriers: Comparison of Shear-Wave Elastography and Transient Elastography with Liver Biopsy Correlation. Leung VY et al. Radiology. 2013 Dec;269(3):910-8.
(3) Diagnostic accuracy of two-dimensional shear wave elastography for the non-invasive staging of hepatic fibrosis in chronic hepatitis B: a cohort study with internal validation. Zeng J et al. Eur Radiol. 2014 Oct;24(10):2572-81.

(4) Accuracy of real-time shear wave elastography for assessing liver fibrosis in chronic hepatitis C: a pilot study. Ferraioli G et al. Hepatology. 2012 Dec;56(6):2125-33.
(5) Liver stiffness in nonalcoholic fatty liver disease: A comparison of Supersonic Shear Imaging, FibroScan and ARFI with liver biopsy. Cassinotto C et al. Hepatology. 2016 Jun;63(6):1817-27.
(6) Non-invasive assessment of liver fibrosis with impulse elastography: Comparison of Supersonic Shear Imaging with ARFI and FibroScan®. Cassinotto C et al. J Hepatol. 2014 Sep;61(3):550-7.
(7) Transient and 2-dimensional Shear-Wave Elastography provide comparable assessment of Alcoholic Liver Fibrosis and Cirrhosis. Thiele M et al. Gastroenterology. 2016 Jan;150(1):123-33.
(8) Evaluation of portal hypertension by real-time shear wave elastography in cirrhotic patients. Kim TY et al. Liver Int. 2015 Nov;35(11):2416-24.
(9) Liver and spleen elastography using supersonic shear imaging for the non-invasive diagnosis of cirrhosis severity and oesophageal varices. Cassinotto C et al. Dig Liver Dis. 2015 Aug;47(8):695-701.
(10) Value of shear wave elastography for predicting hepatocellular carcinoma and esophagogastric varices in patients with chronic liver disease. Kasai Y et al. J Med Ultrason (2001). 2015 Jul;42(3):349-55.
(11) Shear-wave elastography: a noninvasive tool for monitoring changing hepatic venous pressure gradients in patients with cirrhosis. Choi SY et al. Radiology. 2014 Dec;273(3):917-26.

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. In addition to providing exceptional image quality, this unique technology is the foundation of several innovations which have changed the paradigm of ultrasound imaging: ShearWave™ Elastography (SWE™), UltraFast™ Doppler and more recently Angio PL.U.S – Planewave UltraSensitive™ Imaging.

ShearWave Elastography allows physicians to visualize and analyze the stiffness of tissue in a real-time, reliable, reproducible and non-invasive manner. This criteria has become an important parameter in diagnosing potentially malignant tissue or other diseased tissue. As of today, over 300 peer-reviewed publications have demonstrated the value of SWE for the clinical management of patients with a wide range of diseases. UltraFast Doppler combines Color Flow Imaging and Pulsed Wave Doppler into one simple exam, providing physicians with exam results simultaneously and helping to increase patient throughput. The latest innovation, Angio PL.U.S, provides a new level of microvascular imaging through significantly improved color sensitivity and spatial resolution while maintaining exceptional 2D imaging.

SuperSonic Imagine has been granted regulatory clearances for the commercialization of Aixplorer in key 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. SuperSonic Imagine is a listed company since April 2014 on the Euronext, symbol SSI.

For more information about SuperSonic Imagine, please go to www.supersonicimagine.com.

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