

## PRESS RELEASE

## Diagnostic Superiority and Equivalence to Biopsy: a Study Confirms the Clinical Value of ShearWave® Elastography (SWE™) for the Non-Invasive Evaluation of Liver Fibrosis.

*A Chinese multicentric study on patients with chronic hepatitis B results in 2 significant articles: one confirms the superior diagnostic performance of SWE while the other evaluates the combination of radiomic and artificial intelligence techniques applied to SWE imaging, with outstanding results*

**Aix-en-Provence, France, September 24, 2018 – 6pm CEST** - SuperSonic Imagine (Euronext: SSI, FR0010526814, PEA-PME eligible), a company specialising in medical ultrasound imaging (ultrasonography), announced the publication of the results<sup>1</sup> of its prospective multicentric clinical study conducted in China. The results of the study were published in two articles that appeared in the prestigious peer-reviewed journals, **Radiology**<sup>(1)</sup> and **GUT**<sup>(2)</sup>. The objective of the study was to validate the performance of ShearWave® Elastography (SWE™) for the evaluation of liver fibrosis severity in patients with chronic hepatitis B (HBV). SWE is an innovative imaging mode developed by SuperSonic Imagine, which enables tissue stiffness to be instantly visualised and measured (in kPa).

This study collected data from 12 Chinese level 3 hospitals from January 2015 to January 2016. All of the 402 patients included received the same prospective protocol, including a liver biopsy, a SWE examination and a blood test. Some were also assessed with VTCE (Transient Elastography). All images, measurements and histopathological analyses were subjected to centralised quality control, thus ensuring data reliability and consistency.

### **SWE could reduce the need for liver biopsies by 80% in patients with an inactive chronic infection.**

The analysis published in the prestigious north-american journal *Radiology* in July 2018 followed the recent recommendations of the European Association for the Study of the Liver (EASL) pertaining to the care of patients infected with the hepatitis B virus. The patients were divided into two groups: a group of chronic inactive disease, who receive regular monitoring, and a group with active chronic hepatitis who require treatment with antiviral drugs.

Results confirm that SWE is superior to other non-invasive tests to assess fibrosis severity, particularly in case of cirrhosis. In practice, for patients with a chronic inactive hepatitis B infection, a stiffness above 11 kPa could lead to the diagnosis of cirrhosis and thus identifying patients requiring treatment. In contrast, a stiffness below 8.5 kPa could exclude the diagnosis of cirrhosis thus identifying patients requiring monitoring. Although a liver biopsy would still be recommended for a stiffness between 8.5 and 11 kPa, the study demonstrates that the SWE examination could have avoided the need for biopsy in 81.2% of patients (125 out of 154).

“This prospective multicentric study confirmed that two-dimensional SWE is superior to other non-invasive methods in the diagnosis of liver fibrosis and cirrhosis. It also demonstrated that 81.2% of

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<sup>1</sup> Study publicly registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) under number **NCT02313649**

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patients with chronic HBV infection could avoid undergoing a biopsy using SWE.” stated Prof. Ping Liang, MD, principal investigator of the study, from the People’s Liberation Army Hospital in Beijing.

### **Applying radiomic and neural networks methods to SWE images (DLRE) could replace liver biopsy.**

The article published in **GUT**, the leading British gastroenterology journal, reports the results of the use of radiomic and neural network techniques to extract quantifiable features from SWE images (DLRE) to predict fibrosis severity.

The results of this analysis are very promising, given that the diagnostic performance of DLRE was found to be equivalent to the Gold Standard (the biopsy) for determining stages of fibrosis. The DLRE technique could therefore represent an initial step towards standardising practices between radiologists and clinicians, avoiding operator measurements and encouraging the adoption of SWE and DLRE by non-radiological users.

“We were excited to learn about the compelling results of this clinical study and by the resulting published articles confirming SWE’s superior performance in terms of reliability and efficiency. The studies also demonstrated the strong potential for using SWE images combined with artificial intelligence methods to evaluate chronic liver diseases.” explains Michèle Lesieur, Chief Executive Officer at SuperSonic Imagine.

For more information, visit [www.supersonicimagine.com](http://www.supersonicimagine.com).

- (1) The Emerging Role of Two-dimensional US Shear-Wave Elastography in Chronic Liver Disease  
<https://pubs.rsna.org/doi/10.1148/radiol.2018181281>
- (2) Deep learning Radiomics of shear wave elastography significantly improved diagnostic performance for assessing liver fibrosis in chronic hepatitis B: a prospective multicentre study  
<https://gut.bmj.com/content/early/2018/05/04/gutjnl-2018-316204>

### **About SuperSonic Imagine**

SuperSonic Imagine specializes in ultrasound medical imaging. The company manufactures the flagship Aixplorer® series of products, which feature the company’s exclusive UltraFast™ technology. UltraFast™ has given rise to new imaging modes that set the standards of care for non-invasive characterization of breast, liver and prostate diseases. The first groundbreaking UltraFast™ mode developed is ShearWave® Elastography (SWE™), which enables doctors to view and instantly analyze tissue stiffness, a vitally important factor in the diagnosis of many conditions. To date, more than 600 published articles have validated the diagnostic value its technologies.

The most recent addition to the Aixplorer range is the Aixplorer MACH 30® ultrasound platform that introduces the next generation of UltraFast™ imaging, which optimizes the system’s innovative imaging modes: ShearWave PLUS, Doppler UltraFast™, Angio PL.U.S, TriVu ...

The company has more than 2,000 ultrasound systems installed in over 80 countries, its main growth markets are China, the United States and the European Union (France). The company generated a turnover of €24.7 million in 2017, representing annual growth of 11%. SuperSonic Imagine is listed on Euronext (symbol: SSI).

Find out more at [www.supersonicimagine.com](http://www.supersonicimagine.com).

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