Aixplorer® and Aixplorer® Ultimate Ultrasound Diagnostic Systems Receive 510(k) Clearance for Clinical Management of Liver Disease

In the only approval of its kind, indications for use aid non-invasive assessment of hepatic fibrosis and steatosis.

Aix-en-Provence, France, February 1st , 2018 – 7.30 AM CET – SuperSonic Imagine (Euronext: SSI, FR0010526814), a company specializing in ultrasound medical imaging, announced today that the Aixplorer® and Aixplorer® Ultimate ultrasound diagnostic systems have received 510(k) clearance from the U.S. Food and Drug Administration (FDA) as aids to clinical management of patients with liver disease. This additional clearance from the FDA is the only approval of its kind for specific ultrasound imaging capabilities related to liver disease, giving physicians new validated clinical indicators to support using the Aixplorer to non-invasively assess hepatic fibrosis and steatosis.

In addition to routine morphological and hemodynamic imaging, Aixplorer systems can quickly and reliably image and measure liver and spleen stiffness in real time under image guidance, utilizing the platform's ShearWave™ Elastography (SWE) technology. Liver and spleen stiffness are known to be correlated to liver fibrosis severity and are therefore considered critical non-invasive markers of disease severity. Physicians also can use the Aixplorer systems to compare ultrasound liver brightness to a reference tissue and to arrive at a hepato-renal brightness ratio indicating the extent of hepatic steatosis. In addition, Aixplorer's ability to visualize and quantify abdominal vascularization and perfusion will aid clinical management of patients with liver nodules and advanced chronic liver diseases.

"The Aixplorer and Aixplorer Ultimate's ability to measure tissue stiffness is revolutionary, as its color-coded images provide a safe, accurate, non-invasive alternative to biopsy in just 60 seconds." explains Dr. Sumeet Asrani, Hepatologist at Baylor University Medical Center in Dallas Texas. "These advances are exciting from a diagnostic perspective, and their ability to speed diagnosis and reduce the need for invasive biopsy also improve the clinical experience for patients suffering from chronic liver disease."

With their first FDA clearance in 2009 as an ultrasound diagnostic imaging system and with ShearWave™ Elastography capability, Aixplorer products pioneered the field of UltraFast™ ultrasound imaging with global market clearances, and are currently used in 52 countries both in research and routine clinical practice. The additional clearance from the U. S. FDA leverages the results of 130 peer-reviewed publications with SWE on liver disease and extends the routine clinical use of Aixplorer products to the management of liver disease. SuperSonic Imagine continues to demonstrate its strong involvement in the clinical field.

The Aixplorer and Aixplorer Ultimate's capabilities will help physicians on the front lines of liver disease. In 2015, 3.9 million American adults were diagnosed with liver diseases, which were

reported to cause over 38,000 deaths. Chronic liver diseases increase the risk of developing primary liver cancer, a diagnosis received by more than 31,000 Americans in 2014. About 24,600 died from liver cancer in the same year.

In addition, data from 2014 demonstrated that 38% of American adults are obese, and 12% have been diagnosed with diabetes. Both conditions increase the risk of developing non alcoholic steatohepatitis (NASH), a disease partially marked by severe hepatic steatosis and fibrosis.
The additional clearance from the U. S. FDA, obtained by Aixplorer products reinforces SuperSonic Imagine's strategy to focus on the development and commercialization of non-invasive tools to evaluate the severity of NASH.

Ref: https://www.cdc.gov/nchs/fastats/liver-disease.htm

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, Angio PL.U.S – Planewave UltraSensitive™ Imaging and more recently TriVu.

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. 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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