

## SuperSonic Imagine Receives FDA 510(k) Clearance for its new Innovative Breast and Liver package on Aixplorer

*Advances to Aixplorer platform reinforces SuperSonic Imagine's market penetration in the USA for liver and breast*

**Aix-en-Provence, France, November 21, 2016** - SuperSonic Imagine (Euronext: SSI, FR0010526814), a company specializing in ultrasound medical imaging, today announced that it has received 510(k) clearance from the Food & Drug Administration (FDA) for additional probes and significant clinical innovations on the Aixplorer® platform. This authorization includes numerous new imaging modes recently developed by SuperSonic Imagine:

- Angio PL.U.S. - PlaneWave UltraSensitive™ Imaging
- TriVu
- Fusion and Navigation
- Contrast liver imaging
- B-Mode Ratio.

*"This clearance is the culmination of several years of research and development on our Aixplorer platform," said Jacques Souquet, Founder and Chief Innovation Officer for SuperSonic Imagine. "These new imaging modes provide unique information for the clinical management of patients with Breast and Liver disease. In particular, this new release will position SuperSonic Imagine as a leading innovator in the field of chronic liver diseases management and cover the whole spectrum of liver diseases from NAFLD to HCC. We are extremely pleased that we can now bring the latest upgrades to the United States market and its patients and provide the clinical community with the most advanced tools available."*

With ShearWave™ Elastography (SWE™) in use since 2009, Aixplorer allows visualization of liver anatomy in real time, while providing color and quantitative mapping of liver stiffness, an important parameter which helps physician in their imaging of patients with diffuse liver disease such as fibrosis. To date, nearly 100 international publications have demonstrated the reliability and effectiveness of SuperSonic Imagine's SWE in this field. This latest version of Aixplorer ultrasound system will further extend the diagnostic possibilities on patients with chronic liver disease by providing an assessment of the liver echostructure which changes in patients with steatosis. With Angio PL.U.S. and contrast mode, doctors will be able to also visualize the vascularization and micro-vascularization of liver lesions. The fusion and navigation on Aixplorer provides the ability to merge ultrasound images with other imaging modalities (CT, MR, PET), and will allow users to use the equipment in the field of interventional radiology.

Other advancements with this clearance focus on breast imaging. The new breast pack combines new optimized probes and for the first time, a real time TriVu mode which combines anatomical information, stiffness information and Angio PL.U.S. microvascularization information. This mode will offer a comprehensive visualization of breast lesions that had never been proposed in the field of ultrasound.

This new imaging modes and probes cleared by FDA will be showcased on SuperSonic Imagine's booth at RSNA congress (Radiological Society of North America), from November 27 to December 1<sup>st</sup> in Chicago.

### **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](http://www.supersonicimagine.com).

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