Oncoustics Announces Initiation of FDA-Supervised Study of the OnX Liver Assessment Solution at Multiple Clinical Sites

Oncoustics initiates FDA study of the OnX Liver Assessment Solution at clinical sites across the US and Canada marking a milestone in the Company's development.

Oncoustics

TORONTO, ON, CANADA, July 23, 2025 /EINPresswire.com/ -- Oncoustics, the leader in AI-enabled ultrasound-based tissue characterization solutions today announced the initiation of a pivotal clinical study under U.S. Food and Drug Administration (FDA) oversight to evaluate its groundbreaking Software as a Medical Device (SaMD), the OnX Liver Assessment Solution. The study marks a significant milestone in the Company's mission to advance safe, effective, point-of-care solutions addressing the huge unmet clinical needs for liver and metabolic care patients.

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> *Emmanuel Hui, Saltagen Ventures*

The OnX Liver Assessment Solution is an AI-driven prediction tool that uses raw radiofrequency data gathered from a compatible FDA-cleared, point-of-care ultrasound system (POCUS) combined with a standard smartphone. The ensuing study is intended to establish substantial equivalence to the FibroScan® system, a transient elastography based solution that also relies on radiofrequency signals. Clinicians can perform the exam in a single clinical visit and receive a resultant quantitative liver stiffness estimate. Upon clearance, OnX is intended to provide non-invasive estimation of stiffness estimates as an aid to clinical management of adult patients with chronic liver disease, as part of an overall assessment of the liver.

"Oncoustics has re-imagined how ultrasound data can be processed by AI to provide quantitative values to support front line clinicians using low-cost POCUS devices. The complex process behind the OnX, which involved prospectively collecting our own exclusive data set on over 6000

patients, and developing custom deep learning models to mine this extensive data sat - is an engineering milestone," said Ahmed El Kaffas, PhD, cofounder of Oncoustics. "While the technical challenges were vast and many thought that this was not achievable, we delivered on a product that can provide automated quantitative tissue characterization measurements from simple RF ultrasound data to match clinical standard systems."

"The Oncoustics approach is radically different from traditional AI applied to imaging data," said James Wang, General Partner at Creative Ventures. "The data they've collected and the systems they developed are breaking new ground for how AI may be applied to the vast untapped datasets that exist all around us. The true promise of AI in healthcare is not doing better what clinicians can do today; but in interrogating data that human beings could never make sense of to gain clinical insights."

The FDA-supervised study will rigorously assess the OnX's clinical performance against its predicate, its usability, and potential impact on care delivery in real-world settings. The study includes six clinical sites in the US and Canada and one site in Hong Kong and is being monitored by Samuel S. Lee, MD, FRCPC, FAASLD, Emeritus Professor of Medicine University of Calgary, Canada. Dr. Lee is a world renown hepatologist having won several awards including the Charles III Coronation Medal, the Canadian Association of Study of Liver (CASL) Gold Medal, and the CASL Distinguished Service Award. "The promise of Oncoustics to address a growing need in liver care is very exciting. I'm pleased that the company has achieved this milestone, and we look forward to delivering the OnX to hepatology clinics and liver care patients around the world," said Dr. Lee.

"With the FDA's approval of resmetirom last year, NASH/MASH patients now have a viable disease modifying strategy to consider. But detecting liver disease early, putting patients on medication, and monitoring progression remain bottlenecked by expensive or invasive methods such as MRI, elastography, and liver biopsy," said Emmanuel Hui, Partner of Saltagen Ventures and CEO of its affiliated accelerator, Pebble. "Oncoustics' technology fills a key clinical need for patients to evaluate their condition at any point-of-care site. Moreover, a key differentiator for Oncoustics is its truly innovative method in evaluating raw ultrasound acoustic data. This means Oncoustics both creates and utilizes its own goldmine of data, with algorithmic potential for every acoustically accessible indication and organ system."

The study will follow the FDA and International Medical Device Regulators Forum (IMDRF) principles for clinical evaluation of SaMD. As required by FDA guidance, the study design addresses clinical validity, safety, usability, and effectiveness in a side-by-side performance comparison study in collaboration with leading healthcare institutions. Oncoustics expects that study results will support a planned FDA submission, ensuring transparency and evidence for healthcare providers, payers, and patients.

The OnX has not yet been cleared for clinical use and is For Investigational Use Only.

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