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# FDA Grants 510(k) Clearance for Sonic Incytes' Velacur ONE™, AI-Guided Point of Care Ultrasound for the Management of Chronic Liver Diseases

By: Sonic Incytes Medical Corp via Business Wire

August 12, 2025 at 16:26 PM EDT

Sonic Incytes Medical Corp, proudly announces that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for Velacur ONE™, its point-of-care ultrasound elastography device. Building on the success of its original model, Velacur™, Velacur ONE™ introduces an enhanced interface and features for improved portability and user experience. These improvements enable broader scalability to support Sonic Incytes' accelerated US and global expansion strategy. Velacur ONE™ measures attenuation, VDFF (Velacur Determined-Fat Fraction), and liver stiffness using 3D S-WAVE and aids in the management of chronic liver disease including MASH and MASLD.

Velacur ONE™ arrives at a critical time for improved non-invasive testing, following the recent FDA clearance of Rezdifra—the first therapeutic for Metabolic dysfunction–associated steatohepatitis (MASH), a progressive and often underdiagnosed liver disease. In the U.S. alone, an estimated 100 million adults have Metabolic dysfunction–associated Steatotic Liver Disease (MASLD)<sup>1</sup>, with 15–20 million of those affected by MASH<sup>2</sup>. Yet, 90% of MASH cases remain undiagnosed<sup>3</sup>. If left untreated, worsening MASH increases morbidity and may progress to severe complications, including cirrhosis, liver failure, liver cancer, and liver transplant<sup>4,5</sup>. MASH remains challenging to diagnose effectively due to the limitations of existing non-invasive methods, especially those available at the point-of-care.

With the first therapeutic now available and more in the pipeline, clinicians need improved non-invasive tests to diagnose and monitor MASH at point-of-care<sup>6</sup>. Current treatment guidelines for MASH recommend imaging-based elastography, such as Velacur™, to assess liver scarring (fibrosis) and fat content (steatosis). While ultrasound elastography is widely used, when it comes to *treating* patients with MASH, liver stiffness alone cannot be relied on to assess treatment response in the short term<sup>7</sup>. The best predictor of treatment responses was a decrease in steatosis (identified as ≥30% reduction in MRI-PDFF)<sup>8</sup>.

VDFF, Sonic Incytes' proprietary algorithm that received FDA clearance in 2024, demonstrates a strong correlation ( $r = 0.85$ ) with MRI-PDFF—the gold standard for liver fat measurement—and achieves an outstanding accuracy (AUC) of 95% of patients with more than 5% MRI-PDFF, defining the presence of hepatic steatosis<sup>9</sup>. Velacur ONE™ combines this technology with a refined user interface, including B-mode imaging—enabling 3–4x higher reimbursement than non-imaging elastography—and an AI-based organ overlay feature to aid in liver localization, making it the only point-of-care device that estimates both liver stiffness and attenuation that correlates to MRI-PDFF<sup>10</sup>.

*"The launch of Velacur ONE™ marks a pivotal milestone for Sonic Incytes as we accelerate our US and global commercial expansion strategy,"* said Barry Allen, CEO of Sonic Incytes. *"This next-generation device enhances clinical utility and operational scalability, positioning us to better support the growing demand for accessible, non-invasive liver diagnostics and treatment, particularly in the management of MASLD and MASH at the point-of-care."*

## About Sonic Incytes

Sonic Incytes is committed to enhancing patient care through innovative diagnostic solutions. The company's flagship product, Velacur™, equips physicians with an advanced liver imaging tool to help manage the growing epidemic of fatty liver disease. Velacur™ offers real-time, AI-guided quantification of the key markers for

fatty liver disease: liver stiffness, attenuation and VDFF. With real-time results, a low up-front cost and AI guidance, Velacur™ makes liver imaging at the point-of-care affordable and accessible.

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

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<sup>1</sup> American Liver Foundation. (2025, June). Nonalcoholic fatty liver disease (NAFLD). American Liver Foundation

<sup>2</sup> Le P, Tatar M, Dasarathy S, et al. Estimated Burden of Metabolic Dysfunction–Associated Steatotic Liver Disease in US Adults, 2020 to 2050. *JAMA Netw Open*. 2025;8(1):e2454707. doi:10.1001/jamanetworkopen.2024.54707

<sup>3</sup> Fishman, J., Kim, Y., Charlton, M.R. *et al.* Estimation of the Eligible Population For Resmetirom Among Adults in the United States for Treatment of Non-Cirrhotic NASH with Moderate-to-Advanced Liver Fibrosis. *Adv Ther* 41, 4172–4190 (2024). <https://doi.org/10.1007/s12325-024-02989-5>

<sup>4</sup> Friedman SL. Fat, fibrosis, and the future: navigating the maze of MASLD/MASH. *J Clin Invest*. 2025 Apr 1;135(7):e186418. doi: 10.1172/JCI186418. PMID: 40166940; PMCID: PMC11957683.

<sup>5</sup> Fishman J, Alexander T, Kim Y, Kindt I, Mendez P. A clinical decision support tool for metabolic dysfunction-associated steatohepatitis in real-world clinical settings: a mixed-method implementation research study protocol. *J Comp Eff Res*. 2024 Oct;13(10):e240085. doi: 10.57264/ceer-2024-0085. Epub 2024 Sep 20. PMID: 39301878; PMCID: PMC11426282.

<sup>6</sup> Gbadamosi, S. O., Evans, K. A., Brady, B. L., & Hoovler, A. (2025). Noninvasive tests and diagnostic pathways to MASH diagnosis in the United States: a retrospective observational study. *Journal of Medical Economics*, 28(1), 314–322. <https://doi.org/10.1080/13696998.2025.2468582>

<sup>7</sup> Nouredin, M., Charlton, M. R., Harrison, S. A., Bansal, M. B., Alkhouri, N., Loomba, R., Sanyal, A. J., & Rinella, M. E. (2024). Expert panel recommendations: Practical clinical applications for initiating and monitoring resmetirom in patients with MASH/NASH and moderate to noncirrhotic advanced fibrosis. *Clinical Gastroenterology and Hepatology*, 22(12), 2367–2377.

<sup>8</sup> Chen VL, Morgan TR, Rotman Y, Patton HM, Cusi K, Kanwal F, Kim WR. Resmetirom therapy for metabolic dysfunction-associated steatotic liver disease: October 2024 updates to AASLD Practice Guidance. *Hepatology*. 2025 Jan 1;81(1):312-320. doi: 10.1097/HEP.0000000000001112. Epub 2024 Oct 18. Erratum in: *Hepatology*. 2025 Apr 1;81(4):E133.

<sup>9</sup> Honarvar, M., Lobo, J., Schneider, C., Klein, S., Smith, G. I., Loomba, R., Ramji, A., Hassanein, T., Yoshida, E. M., Pang, E., Curry, M. P., & Afdhal, N. H. (2024). Methods and validation of Velacur determined fat fraction in patients with MASLD. *WFUMB Ultrasound Open*, 2(2), Article 100061.

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The launch of Velacur ONE™ marks a pivotal milestone for Sonic Incytes as we accelerate our US and global commercial expansion strategy.

## Contacts

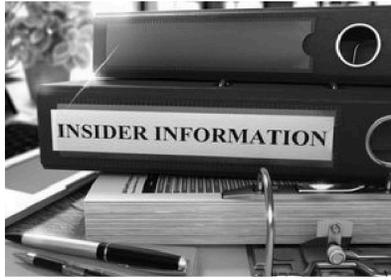
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