

Agitated Solutions, Inc. Receives Fast Track Designation for Investigational Drug ASI-02

ASI-02 is a Novel Contrast Agent for Cardiac Bubble Studies

ST. PAUL, MN, UNITED STATES, October 23, 2025 /EINPresswire.com/ -- [Agitated Solutions, Inc.](#)

(ASI), a medical technology company developing innovative tools to enhance ultrasound imaging and diagnostic accuracy across multiple clinical applications, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its inaugural product, ASI-02.

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We are honored to receive this important recognition from the FDA for our contrast agent, ASI-02.”

Morgan Evans, CEO, Agitated Solutions, Inc.

ASI-02 is a novel ultrasound contrast agent designed for use in saline contrast echocardiography. The FDA’s Fast Track designation is intended to accelerate the review and approval of promising treatments that address serious

conditions with unmet clinical needs.

ASI is conducting a multicenter, randomized clinical trial, the “ENHANCE” trial, focused on assessing the safety and efficacy of ASI-02 in up to 300 patients undergoing transthoracic echocardiography (TTE) with agitated saline contrast, commonly referred to as a “cardiac bubble study,” in the United States and Canada. The current standard of care involves a mixture of saline and air that is manually agitated to create microbubbles which are then injected into a vein to visualize blood flow in the right side of the heart. Once injected the microbubbles become visible under ultrasound and help cardiologists identify right-to-left shunts, which cause improper blood flow and can be a leading cause of stroke, particularly in people under 60 years of age. The ENHANCE trial will evaluate the new agent compared to the standard agitated saline method in its diagnostic capability.

“We are honored to receive this important recognition from the FDA for our contrast agent, ASI-02,” said Morgan Evans, Co-Founder and Chief Executive Officer of Agitated Solutions, Inc. “By earning Fast Track designation, we are one step closer to providing a right-heart diagnostic tool designed to simplify the sonographer’s workflow and enhance diagnostic accuracy for cardiologists and patients.”

About Agitated Solutions, Inc.

Agitated Solutions is developing a portfolio of products to enhance the use of ultrasound

imaging, improve efficiency and clinical outcomes. The Company's platform includes a proprietary ultrasound contrast agent, workflow streamlining accessories, and AI-enabled software solutions that aim to improve image quality and enhance diagnostics. ASI-02 is an investigational new drug and is not approved for use in the U.S. outside of this IND. It is currently approved for use in Canada.

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