Agitated Solutions Enrolls First Patient in Phase 3 'ENHANCE' Trial of Novel Contrast Agent for Cardiac Bubble Studies

First patient has been enrolled at Northwestern University by cardiologist Akhil Narang, M.D.

ST. PAUL, MN, UNITED STATES, November 6, 2025 /EINPresswire.com/ -- • Agitated Solutions, Inc.'s ASI-02 is intended to opacify the right heart and to aid in detection of right-to-left shunts in patients who are clinically indicated for a saline contrast echocardiography study (cardiac bubble study).

• ASI-02 is an innovative technology designed to address image quality, reduce study variability, and improve workflow for cardiac bubble studies.

> The data we collect from this trial will support the safety and effectiveness of our novel, right-heart contrast agent and build on our early commercial experience in Canada."
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> *Morgan Evans, CEO, Agitated Solutions, Inc.*

• The first patient has been enrolled at Northwestern University by cardiologist Akhil Narang, M.D. in the Phase 3, multi-center, randomized, blinded, cross-over trial evaluating the safety and efficacy of ASI-02 compared to manually agitated saline standard of care.

Agitated Solutions, Inc., a medical technology company developing tools to improve ultrasound imaging and aid in diagnosis across multiple clinical applications, has announced the first patient enrollment in its Phase 3 clinical trial. The multicenter, randomized "ENHANCE" study is focused on assessing the safety and efficacy of ASI-02 in patients undergoing transthoracic echocardiography (TTE) with agitated saline contrast—commonly referred to as a "cardiac bubble study"—in the United States and Canada. The first patient was enrolled at Northwestern University.

"We are excited to begin this important trial," said Akhil Narang, M.D., Director, Echocardiography Laboratory, Division of Cardiology at Northwestern University and Principal Investigator for the trial. "There is a strong need for more consistent saline contrast to improve image quality and facilitate diagnoses in cardiac bubble studies. This new contrast agent has the potential to

streamline workflows, allowing for greater ease of use in the echo lab."

Cardiac bubble studies are the current standard of care for diagnosing right-to-left shunts, which cause improper blood flow and can be a leading cause of cryptogenic stroke, particularly in people under 60 years of age. To conduct a bubble study, saline is manually mixed with air to produce a solution containing microbubbles that are injected into the patient. The temporary bubbles travel to the right side of the heart where they can be viewed under ultrasound and are absorbed within the lungs. Visualization of bubbles in the left heart aid in the detection of a shunt. These studies require one clinician to agitate and inject the saline while a second captures the images, making them resource intensive and time-consuming. This manual process also generates variable and inconsistent bubbles that dissipate more quickly which can impair accurate patient diagnosis.

"We are delighted to announce we have initiated the ENHANCE trial for ASI-02," said Morgan Evans, CEO of Agitated Solutions. "The data we collect from this trial will support the safety and effectiveness of our novel, right-heart contrast agent and build on our early commercial experience in Canada."

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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