Stereotaxis Announces EU Launch and 510(k) Submission for Synchrony System to Modernize Interventional Cath Labs

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ST. LOUIS, Oct. 15, 2025 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced it obtained CE Mark in Europe and submitted a 510(k) application to the FDA in the US for the Synchrony™ system.

Synchrony is designed to digitize and modernize the interventional cath lab. Synchrony's slim and stunning 55" 4K ultra-high-definition display consolidates the viewing and control of all disparate systems in the lab, offering an enhanced procedure experience with custom layouts, streamlined workflows, an intuitive user interface, and a decluttered environment. Synchrony digitizes the video streams with full fidelity and less than a single frame latency, offering crystal-clear visualization. Its architecture allows obsolescence protection for labs as new technologies are introduced in the future. Synchrony is made available with SynX™, a cloud-based HIPAA and GDPR-compliant app that allows for secure remote connectivity, collaboration, recording, and monitoring of the cath lab.

"In my role managing the technology across our electrophysiology labs and advising labs across the country, I have significant experience with the various interventional lab display offerings," said Matthew Dare, CEPS, Research and Technology Coordinator, Texas Cardiac Arrhythmia Institute at St. David's Medical Center in Austin, Texas. "The underlying hardware and software architecture of Synchrony and SynX is far beyond what anyone else has developed. It promises a better intraoperative experience for physicians and nurses, improved equipment reliability and maintenance, and attractive tools for managing a cardiovascular program with remote monitoring, collaboration and recordings."

"We have long recognized the importance of remote connectivity and collaboration for our EP labs," said Dr. Jim Cheung, Professor of Medicine and Director of Cardiac Electrophysiology Fellowship and Research at Weill Cornell Medicine in New York City. "Technologies to date though have not made reliable high-quality connectivity easy. SynX provides a much-needed solution that can permit seamless collaboration across labs and enhance our ability to ensure the best patient care and to train the next generation of physicians."

Synchrony and SynX have been engineered to be foundational platforms for future innovations. The advanced architecture enables future applications and the leveraging of artificial intelligence for enhanced clinical insights, automation, and safety.

"Synchrony and SynX are central to our digital surgery efforts to modernize the interventional lab with enhanced workflow, remote connectivity, and smart AI capabilities," said David Fischel, Stereotaxis Chairman and CEO. "The technology improves the robotic cockpit, and will be critical in supporting future robotic efforts for remote long-distance procedures and automated catheter navigation. The opportunity is much broader than robotic labs as we believe all cath labs stand to benefit from improved workflow, connectivity, and collaboration."

About Stereotaxis
Stereotaxis (NYSE: STXS) is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, expand access to minimally invasive therapy, and enhance the productivity, connectivity, and intelligence in the operating room. Stereotaxis technology has been used to treat over 150,000 patients across the United States, Europe, Asia, and elsewhere. For more information, please visit www.stereotaxis.com.

This press release includes statements that may constitute "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Act of 1934, including statements regarding the completion of the Company's offering and the anticipated use of proceeds therefrom, usually containing the words "believe", "estimate", "project", "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to manage expenses at sustainable levels, acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its technology, competitive factors, changes resulting from healthcare policy, dependence upon third-party vendors, timing of regulatory approvals, the impact of pandemics or other disasters, and other risks discussed in the Company's periodic and other filings with the SEC. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this press release. There can be no assurance that the Company will recognize revenue related to customer purchase orders and other commitments because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control and may be revised, modified, delayed, or canceled.

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