GenesisX Robotic Magnetic Navigation System Receives U.S. FDA Clearance

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ST. LOUIS, Nov. 10, 2025 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that it received U.S. Food and Drug Administration 510(k) clearance for its latest generation robotic system, GenesisX™.

GenesisX is the latest advance in endovascular surgical robotics, building upon the established benefits of Robotic Magnetic Navigation while significantly enhancing the accessibility of the technology for healthcare providers. The system features a compact and efficient design, incorporating magnetic shielding into its structure in place of the shielding otherwise installed in the walls of the operating room. It operates on standard 120/230V power, requires no structural anchoring, and features an 80% smaller system cabinet. These allow for GenesisX to be installed in existing non-modified cath labs without complex architectural planning or construction. The system's smaller and lighter design enhances workflow efficiency while maintaining the highest standards in speed and responsiveness.

"This is a landmark approval as we transform the accessibility and scalability of Robotic Magnetic Navigation, pioneering broad robotic adoption across endovascular surgery," said David Fischel, Chairman and CEO of Stereotaxis. "We thank and congratulate all those who helped us reach this milestone. Successful development, approval, and deployment of complex surgical robots that operate reliably in daily clinical use is a unique expertise. This is our second robotic system launched within five years, reflecting our commitment and capacity to drive significant innovation in electrophysiology and endovascular medicine."

"For years, challenging infrastructure demands limited the adoption of robotic technology amongst the community of physicians interested in its clinical benefits," said Dr. Francis Marchlinski, Professor of Medicine and Director of Electrophysiology at the University of Pennsylvania Health System. "The GenesisX design changes that by dramatically simplifying installation. This helps to more readily bring the precision of robotic navigation and its ease of use for the operator to a broader patient population."

Stereotaxis has initiated a limited launch of GenesisX in the United States and Europe while simultaneously expanding its portfolio of compatible catheters, enhancing compatibility with various x-rays, demonstrating commercial use, and enhancing supply chain, manufacturing, installation and commercial processes for a full launch. GenesisX's flexibility as a capital system provides opportunities for alternative financing models including sales, leases and pay-per-use.

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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