Stereotaxis Achieves CE Mark in Europe and Submits 510(k) in the US for Next Generation Robotic System GenesisX

August 12, 2024

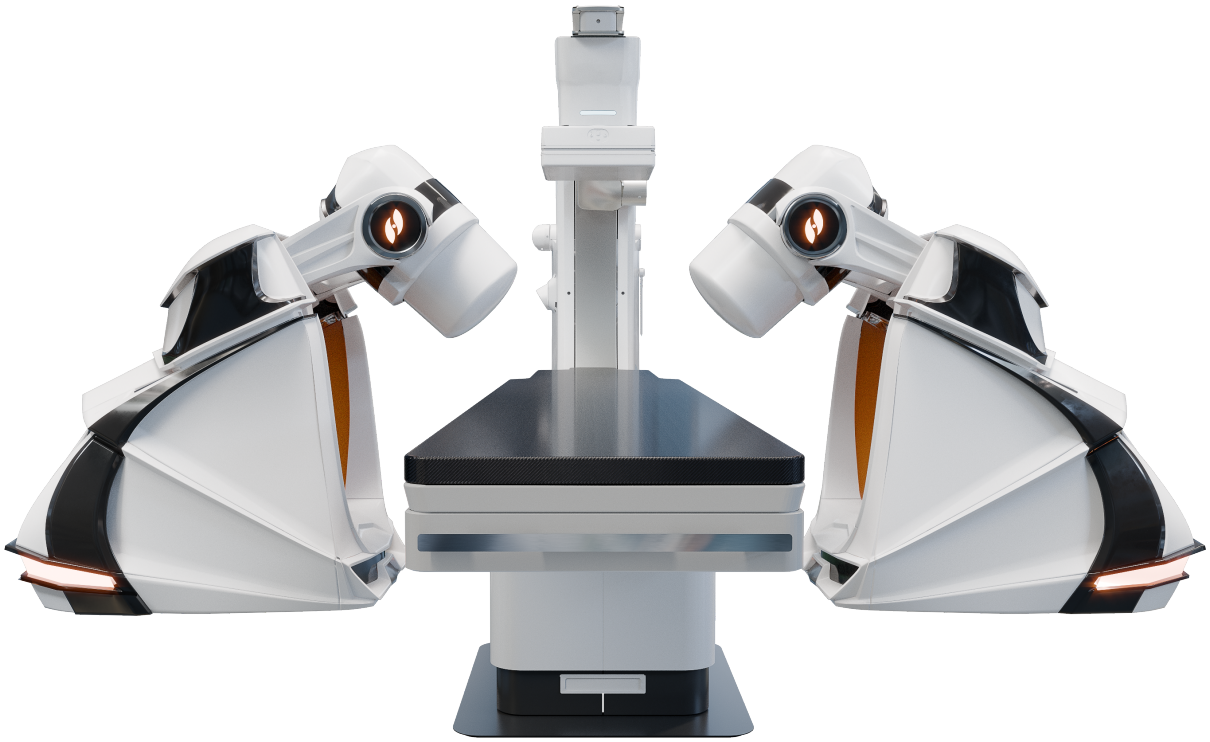
- Latest innovation in Robotic Magnetic Navigation technology supports broad accessibility of robotics for minimally-invasive endovascular surgery
- GenesisX has obtained CE mark in Europe and has been submitted to the FDA for 510(k) clearance in the United States

ST. LOUIS, Aug. 12, 2024 (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 a next generation robotic system, GenesisX.

"We are excited to introduce GenesisX and share the achievement of these significant milestones," said David Fischel, Chairman and CEO. "Medical innovation only realizes its full potential to advance and improve patient care if it is designed to be broadly accessible. The clinical value of Stereotaxis' robotic technology has been extensively demonstrated yet difficult to access for the vast majority of interested physicians and hospitals. GenesisX is strategically transformative as it supports broad adoption of robotics in electrophysiology and across endovascular interventions."

GenesisX builds upon the established benefits and performance of Robotic Magnetic Navigation (RMN) systems, while reducing the complexities and barriers to hospital adoption of the technology. Preparing an operating room to accommodate a RMN system has typically required significant structural modification, including the installation of thousands of pounds of magnetic shielding in the walls, reinforcement of the floor, high electrical power, and extensive cabling through conduits between the operating room and a dedicated cabinet room. This entailed months of planning and coordination between site planners, architects, and contractors. GenesisX utilizes smaller magnets and incorporates magnetic shielding into its structure in place of the shielding otherwise installed in the walls of the operating room. It requires no structural anchoring through the floor and operates using standard 120/230V power outlets. A single fiber is routed from each robot to the system cabinet, which is 80% smaller than the cabinet of Genesis and can fit under a table in the operating room. GenesisX is smaller and lighter than any previous generation system, and maintains the speed, responsiveness, and efficient workflow of Genesis. GenesisX will serve as a platform for additional innovations in the future.

GenesisX has obtained CE mark in Europe and has been submitted to the FDA for 510(k) clearance in the United States. Stereotaxis plans to use the coming months to gain regulatory approval for compatible catheters, demonstrate real-world use of the system, enhance compatibility with various x-rays, and prepare supply chain, manufacturing, installation and commercial processes for a full launch and significant adoption of GenesisX in 2025.



GenesisX Robotic Magnetic Navigation System



Magnetic shielding built into the structure of the GenesisX Robotic Navigation System

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 100,000 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, 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 statements relating to our recent acquisition of APT, including any benefits expected from the acquisition, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its 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.

Stereotaxis Contacts:
David L. Fischel
Chairman and Chief Executive Officer

Kimberly Peery
Chief Financial Officer

314-678-6100
Investors@Stereotaxis.com

Photos accompanying this announcement are available at

https://www.globenewswire.com/NewsRoom/AttachmentNg/b2a52dbd-2ea2-4a04-a6b3-28f48b832d8c

https://www.globenewswire.com/NewsRoom/AttachmentNg/739addac-9797-49cf-b274-3c1eae48bda2

Source: Stereotaxis, Inc.

GenesisX Robotic Magnetic Navigation System



GenesisX Robotic Magnetic Navigation System

Magnetic shielding built into the structure of the GenesisX Robotic Navigation System



Magnetic shielding built into the structure of the GenesisX Robotic Navigation System