Stereotaxis Earns FDA Clearance and Announces U.S. Launch of Genesis Robotic Magnetic Navigation System

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ST. LOUIS, March 06, 2020 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), the global leader in innovative robotic technologies for the treatment of cardiac arrhythmias, announced today it has received U.S. Food and Drug Administration (FDA) 510(k) clearance of the Genesis RMN® System for the robotic navigation of magnetic ablation catheters to treat heart rhythm disorders.

“Genesis is a leap forward in Robotic Magnetic Navigation technology,” said David Fischel, Chairman and CEO. “We are confident Genesis will have a meaningful impact on patients, physicians, and providers in Electrophysiology. Genesis is a reflection of our commitment to positively transform interventional medicine with robotics.”

Tens of millions of individuals worldwide suffer from arrhythmias. When left untreated, certain arrhythmias can significantly increase the risk of stroke, heart failure, and sudden cardiac arrest. Robotic Magnetic Navigation (RMN) introduces the benefits of robotic precision and safety to cardiac ablation, a common minimally invasive procedure to treat arrhythmias. More than 100,000 patients have been treated using Stereotaxis’ RMN technology in more than 100 hospitals around the world. Over 350 scientific publications have documented the technology’s clinical value.

The Genesis RMN System builds upon the established benefits and reliability of RMN in an innovative architecture that is faster, smaller, lighter and more flexible. It utilizes smaller magnets rotated along their center-of-mass for increased speed and control. Across a broad range of navigational routines, the Genesis System is 70% to 80% faster than its predecessor. The system’s significant size reduction is designed to improve the patient experience while on the operating table, provide physicians and nurses with greater access to the patient during the procedure, and increase space in the labs for an enhanced work environment. The magnets are held on flexible and rugged robotic arms, increasing the potential range of motion of the system and serving as a platform from which future innovations in other clinical specialties may be possible. The Genesis RMN System has FDA clearance to navigate an array of compatible interventional devices broadly within all chambers of the heart and coronary vasculature, and throughout the neuro and peripheral vascular system.

Genesis is integrated and available with Stereotaxis Imaging Model S, an x-ray system designed for electrophysiology with modern, digital flat-panel detector technology to support radiation reduction and clear image quality. The combined systems are designed to reduce the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice. Stereotaxis will serve as the single source for architectural planning, installation, and ongoing servicing and maintenance of the combined technologies, providing a more efficient, responsive, and cost-effective solution.

About Stereotaxis
Stereotaxis is the global leader in innovative robotic technologies designed to enhance the treatment of arrhythmias and perform endovascular procedures. 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, improved lab efficiency and productivity, and enhanced integration of procedural information. The core components of Stereotaxis’ systems have received regulatory clearance in the United States, European Union, Japan, Canada, China, 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 from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to raise additional capital on a timely basis and on terms that are acceptable, its ability to continue to manage expenses and cash burn rate at sustainable levels, continued 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 systems and the timing of such purchases, competitive factors, changes resulting from healthcare reform in the United States, including changes in government reimbursement procedures, dependence upon third-party vendors, timing of regulatory approvals, 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 in any particular period or at all because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control. In addition, these orders and commitments may be revised, modified, delayed or canceled, either by their express terms, as a result of negotiations, or by overall project changes or delays.

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