Stereotaxis Submits First Ever Robotically Navigated High-Density EP Mapping Catheter for Regulatory Clearance

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ST. LOUIS, March 03, 2025 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced FDA regulatory submission for the MAGiC Sweep™ catheter. MAGiC Sweep is the first high-density EP mapping catheter developed to be robotically navigated using Stereotaxis' Robotic Magnetic Navigation systems.

High density mapping has transformed the EP field, enhancing cardiac ablation procedures by enabling more efficient, detailed and precise identification of arrhythmia origin. The combination of high-density mapping with robotics is designed to offer multiple improvements over what has been available: highly rapid and detailed electroanatomical mapping collected simultaneously from 20 electrodes, mapping with the inherent safety of an atraumatic catheter, the ability to map otherwise difficult to reach areas of the heart, improved robotic procedural workflow, and more anatomically accurate maps by avoiding the distension caused by rigid catheters. Stereotaxis' robotic technology allows for automated mapping that will be enhanced in combination with MAGiC Sweep.

"The development of the first ever robotically navigated high-density mapping catheter is a major milestone for the EP field," said Dr. Roderick Tung, Chief of Cardiology and Director of Cardiovascular Clinical Research at The University of Arizona College of Medicine - Phoenix. "Mapping with multi-electrode catheters has taught us so much in both mechanism and therapy for both atrial and ventricular arrhythmias. Remaining limited to only point-by-point mapping has held back the adoption of robotic navigation, as we have become accustomed to seeing human arrhythmias in exquisitely high resolution. We look forward to the positive impact we expect MAGiC Sweep to have on our patients and new possibilities in the field."

Stereotaxis submitted a 510(k) application for MAGiC Sweep with the FDA and expects to submit MAGiC Sweep for European CE Mark clearance this month. MAGiC Sweep was designed and is manufactured by Stereotaxis' fully-owned subsidiary Access Point Technologies in Minnesota. Stereotaxis expects to initiate a broad commercial launch of MAGiC Sweep following anticipated approvals in the second half of this year. This is the first dedicated diagnostic catheter made available for Stereotaxis' robotic technology, complementing robotic ablation catheter innovations.

"Stereotaxis is rapidly evolving towards becoming a robotic leader with a broad portfolio of proprietary differentiated catheters," said David Fischel, Stereotaxis Chairman and CEO. "The acquisition of Access Point Technologies reflected our commitment to this strategy and has accelerated our progress. The submissions of MAGiC Sweep – along with our first vascular guidance catheter EMAGIN 5F, announced in a separate press release this morning – reflect the first tangible milestones in this strategic transformation."

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, 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, 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.

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