Stereotaxis to Initiate First-in-Human Trial to Support CE Mark Application of MAGiC Catheter

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ST. LOUIS, June 15, 2023 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that it intends to initiate a first-in-human trial to support the CE Mark submission for its MAGiC™ catheter.

Stereotaxis' MAGiC catheter is a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures. The catheter's CE Mark submission was made in July 2022 and included substantial in vivo preclinical, lab and bench data. The submission strategy was in-line with multiple historical precedents for similar ablation catheters as well as verbal feedback provided by the European Notified Body. Given evolving interpretation of recent EU Medical Device Regulation, the Notified Body has now requested clinical data to support the submission. Stereotaxis intends to complete a first-in-human study to support the MAGiC submission before the end of this year.

"We look forward to advancing the MAGiC catheter into clinical use and are working expeditiously to ensure the technology becomes available to patients and the electrophysiology community as soon as possible," said David Fischel, Stereotaxis Chairman and CEO.

"Stereotaxis continues to experience demand for its Genesis robotic system, and reiterates its expectation of double-digit revenue growth in 2023. Our strong financial position allows us to advance a robust innovation strategy through commercialization without the need for additional financing. This innovation strategy, including a highly-accessible robot with proprietary interventional catheters for use in electrophysiology and broadly across endovascular interventions, serves as the foundational product ecosystem to transform endovascular surgery with robotics."

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 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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Pioneering Endovascular Robotics

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