

Stereotaxis Announces Regulatory Submissions of the MAGiC Ablation Catheter in Europe and the United States

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ST. LOUIS, March 04, 2024 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that regulatory submissions were made recently in both Europe and the United States for the MAGiC[™] catheter. These submissions follow successful initial clinical results in an ongoing trial.

Stereotaxis' MAGiC catheter is a robotically navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures. Building on the experience gained through over 100,000 procedures during the course of nearly twenty years with existing robotically navigated ablation catheters, MAGiC incorporates various features that are designed to enhance patient safety, procedural effectiveness and efficiency, and the physician experience.

The first human procedures with the MAGiC catheter commenced earlier this year as part of a prospective multi-center clinical study. Stellar initial results during the first 20 procedures were submitted for publication to a leading Electrophysiology journal, with the authors documenting 100% acute efficacy and no adverse events. These results were included in the regulatory submissions.

The CE Mark and PMA Supplement submissions of the MAGiC catheter reflect the culmination of an extensive design, development, manufacturing and testing effort. The catheter is the first in a series of interventional devices being developed by Stereotaxis and serves as a platform for future innovations. Stereotaxis anticipates making the MAGiC catheter commercially available for the community of robotic electrophysiologists following receipt of regulatory clearances.

"We are excited to have reached this significant milestone for Stereotaxis and for the physician community that is pioneering the frontiers of robotics in electrophysiology," said David Fischel, Stereotaxis Chairman and CEO. "We look forward to working collaboratively with the regulatory agencies during their review of our submissions and hope to make the benefits of MAGiC available to patients and physicians in the near future."

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 <u>www.Stereotaxis.com</u>.

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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