Stereotaxis Receives CE Mark Recertification Under EU's MDR Regulatory Framework

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ST. LOUIS, May 24, 2024 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that it has received CE Mark recertification under the European Union's new Medical Device Regulation (MDR) regulatory framework. The recertification under MDR covers all Stereotaxis devices currently available in Europe.

MDR (Regulation (EU) 2017/745) replaces the former European Medical Device Directive, which had governed the approval and marketing of medical devices in the EU. The new regulation includes more stringent standards and requirements across quality, clinical and post-market surveillance areas. It is intended to create a robust regulatory framework for improved clinical safety and market access for medical devices. Stereotaxis has now received its updated EU Quality Management System Certificate. This certificate shows that the Stereotaxis Quality System is in accordance with MDR and that Stereotaxis' products now have a valid CE Mark under MDR. This MDR certification will support regulatory clearances of upcoming innovations.

"This final step in the certification of our products and quality systems under MDR is the culmination of several years of diligent work by the Stereotaxis team," said Matthew Stepanek, Sr. Director of Regulatory Affairs, Quality & Technical Writing. "We appreciate the collaboration with our Notified Body in this entire process."

"This is a reflection of Stereotaxis' commitment to high-quality devices, systems, and processes to ensure the best possible experience for the patients and physicians that rely on our technology," said David Fischel, Chairman and CEO. "Congratulations to all those at Stereotaxis who made this possible."

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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