Stereotaxis Initiates Multi-Center Randomized Superiority Study on Ventricular Tachycardia Ablation Outcomes

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Compares Magnetic Navigation to Manual Techniques for the Treatment of VT

ST. LOUIS, Jan. 11, 2016 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (NASDAQ:STXS), a global leader in innovative technologies for the treatment of cardiac arrhythmias, today announced that it has initiated its first prospective, multi-center, randomized clinical study to compare radiofrequency ablation outcomes generated using its Niobe® ES remote magnetic navigation system to manual approaches in ischemic scar ventricular tachycardia (VT) patients. VT is a rapid heart rhythm that, if left untreated, may lead to ventricular fibrillation and sudden cardiac death. It is estimated that approximately 60,000 ablations are performed annually on a worldwide basis to treat VT, with that number increasing by over 10% each year. In 2015, approximately 2,300 of these 60,000 procedures were performed using the *Niobe* system.

"The *Niobe* system is uniquely well-suited for the treatment of arrhythmias in difficult-to-reach, complex anatomy, such as VT, and has an outstanding performance record in safety, acute success and long-term results with VT ablation," said William C. Mills, Stereotaxis Chief Executive Officer. "We believe this superiority study will provide definitive evidence of the improved long-term patient outcomes that physicians realize with the *Niobe* system in treating VT compared to manual approaches."

Researchers from U.S. and European sites will conduct a prospective, post-market, randomized controlled trial involving 382 patients and designed to establish the superiority of VT ablation outcomes using the *Niobe* ES system versus a manual approach in a low ventricular ejection fraction population. The study, named the "MAGNETIC VT" study, will be led by Global Principal Investigator Dr. Andrea Natale, Executive Medical Director, Texas Cardiac Arrhythmia Institute of St. David's Medical Center, along with Co-Principal Investigators Dr. Tamas Szili-Torok from Erasmus Medical Center of the Netherlands, and Dr. Roderick Tung from The University of Chicago Medicine. Ten hospitals have confirmed participation. The study can be expanded to another five hospitals at the discretion of the study's sponsor and principal investigators.

Dr. Natale and a group of U.S. physicians recently conducted a multi-center, retrospective study comparing long-term success rates with the *Niobe* system and manual approaches in VT. The findings of that study revealed a substantially greater long-term success rate among the *Niobe* patient group (81.2% vs. 69%) and were published at the American Heart Association Scientific Sessions.

"Finding the optimal treatment for VT is a very important clinical topic, and the MAGNETIC VT study is one of the few randomized clinical trials being conducted around the world that can lead to meaningful insights on the topic. Through this upcoming study, we have the opportunity to determine if treatment of VT with the *Niobe* system is superior to manual approaches, which would further support its classification as the standard of care," said Dr. Natale.

Patient enrollment is expected to begin shortly, with follow-up occurring at three, six, nine and twelve months. The primary endpoint is freedom from any recurrence of VT through one year. Participating centers, each considered VT centers of excellence, include:

- Advocate Christ Medical Center (Oak Lawn, IL)
- Algemeen Ziekenhuis (Brugge, Belgium)
- Erasmus Medical Center (Rotterdam, Netherlands)
- Medical College of Georgia (Augusta, GA)
- Intermountain Medical Center (Murray, UT)
- Nemocnice Na Homolce (Prague, Czech Republic)
- Rigshospitalet (Copenhagen, Denmark)
- St. David's Medical Center (Austin, TX)
- The University of Chicago Medicine (Chicago, IL)
- The University of Kansas Hospital (Kansas City, KS)

About Stereotaxis

Stereotaxis is a healthcare technology and innovation leader in the development of robotic cardiology instrument navigation systems designed to enhance the treatment of arrhythmias and coronary disease, as well as information management solutions for the interventional lab. Over 100 issued patents support the Stereotaxis platform, which helps physicians around the world provide unsurpassed patient care with robotic precision and safety, improved lab efficiency and productivity, and enhanced integration of procedural information. Stereotaxis' core *Epoch*® Solution includes the *Niobe*® ES remote magnetic navigation system, the *Odyssey*® portfolio of lab optimization, networking and patient information management systems, and the *Vdrive*® robotic navigation system and consumables.

The core components of Stereotaxis' systems have received regulatory clearance in the United States, European Union, Canada, China, Japan, and elsewhere. The V-Sono ™ ICE catheter manipulator, V-Loop ™ variable loop catheter manipulator, and V-CAS ™ catheter advancement system have received clearance in the United States, Canada, and the European Union. For more information, please visit www.stereotaxis.com.

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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, its ability to continue to work with lenders to extend, repay or refinance indebtedness on acceptable terms, 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 the recently enacted 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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