AtriCure Announces the First Patient Treated in the LeAAPS™ Clinical Trial

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Trial will evaluate the safety and effectiveness of the AtriCure AtriClip® Left Atrial Appendage Exclusion System for stroke prevention in cardiac surgery patients

MASON, Ohio--(BUSINESS WIRE)--Jan. 31, 2023-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments and therapies for atrial fibrillation (Afib), left atrial appendage (LAA) management and post-operative pain management, today announced that the first patient was treated in the Left Atrial Appendage Exclusion for Stroke Prevention (LeAAPS™) clinical trial (NCT 05478304). The patient was treated by U.S. co-principal investigator Dr. Marc Gerdisch at Franciscan St. Francis Heart Center in Indianapolis, Indiana.

LeAAPS is a prospective, randomized, blinded, superiority, investigational device exemption (IDE) clinical trial to evaluate the safety and effectiveness of the AtriClip® LAA Exclusion System for the prevention of ischemic stroke or systemic arterial embolism in cardiac surgery patients at elevated risk for these events and with no history of Afib, which represents a significant proportion of the market. The trial will enroll up to 6,500 patients at up to 250 centers worldwide, making it the largest randomized clinical trial for surgical LAA exclusion. LeAAPS is intended to inform and better define clinical practice and treatment guidelines for stroke prevention in patients undergoing planned cardiac surgery with an elevated risk of ischemic stroke and systemic embolism.

“The LeAAPS trial is a landmark study to evaluate the prophylactic use of AtriClip devices for stroke reduction in cardiac surgery patients without a preoperative Afib diagnosis, laying the groundwork for a new frontier in stroke prevention,” said Michael Carrel, President and CEO of AtriCure. “We have an impressive roster of world-class physicians and hospitals that will be enrolling patients, and we see a substantial opportunity to leverage the AtriClip platform for better long-term outcomes in this patient population while expanding our markets.”

AtriCure first entered the LAA market upon FDA 510(k) clearance of the AtriClip System in 2010. Today, AtriClip System products are the most widely used LAA management devices worldwide. AtriCure plans to use LeAAPS trial results to expand the labeled indications for use of the AtriClip System to include stroke prevention in patients with elevated risk of ischemic stroke events.

The trial will be completed in collaboration with the Population Health Research Institute (PHRI), which is associated with McMaster University in Hamilton, Ontario. PHRI is a clinical research organization that has organized an extensive international network of committed collaborators in 102 countries. PHRI has significant experience and expertise designing and executing large, clinical studies.

“LeAAPS is one the largest randomized controlled trials in cardiac device history, and we expect it will establish a new standard of care for patients undergoing cardiac surgery,” said Dr. Richard Whitlock, Cardiothoracic Surgeon, McMaster University, and Global Principal Investigator for the trial. “A fantastic multidisciplinary team has designed the trial, and we’re all excited to advance the understanding of atrial disease, atrial fibrillation and stroke.”

About AtriCure

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 37 million people worldwide. Electrophysiologists and cardiothoracic surgeons around the globe use AtriCure technologies for the treatment of Afib and reduction of Afib related complications. AtriCure’s Isolator ® Synergy™ Ablation System is the first medical device to receive FDA approval for the treatment of persistent and long-standing persistent Afib. AtriCure’s AtriClip ® Left Atrial Appendage Exclusion System products are the most widely sold LAA management devices worldwide. AtriCure’s Hybrid AF™ Therapy is a minimally invasive procedure that provides a lasting solution for long-standing persistent Afib patients. AtriCure’s cryoICE cryoSPHERE ® probe is cleared for temporary ablation of peripheral nerves to block pain, providing pain relief in cardiac and thoracic procedures. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

Forward-Looking Statements

This press release contains “forward-looking statements”– that is, statements related to future events that by their nature address matters that are uncertain. Actual results could differ materially. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, visit http://www.atricure.com/forward-looking-statements as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We assume no obligation to update any forward-looking statements contained in this release as a result of new information or future events or developments, except as may be required by law.

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