AtriCure Announces the First Patient Enrolled in the ICE-AFIB™ Clinical Trial

February 5, 2019

Trial will evaluate the safety and effectiveness of AtriCure's cryoICE ® Ablation System for the treatment of persistent and long-standing persistent atrial fibrillation in open concomitant cardiac surgery

MASON, Ohio--(BUSINESS WIRE)--Feb. 5, 2019-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatment for atrial fibrillation (Afib) and left atrial appendage management, today announced the first patient was treated in the ICE-AFIB™ trial (NCT03732794). Following Investigational Device Exemption (IDE) approval by the FDA, the first patient was treated by Dr. Niv Ad, at Washington Adventist Hospital in Takoma Park, Maryland. The trial will evaluate the safety and effectiveness of the cryoICE Ablation System for the treatment of persistent and long-standing persistent atrial fibrillation during concomitant open-chest cardiac surgery.

The ICE-AFIB trial is a prospective, multicenter, single-arm study of up to 150 patients at up to 20 U.S. centers. The study will enroll patients with persistent and long-standing persistent atrial fibrillation undergoing cardiac surgical procedure(s) for heart valve repair or replacement and/or coronary artery bypass procedures. The study defines persistent and long-standing persistent atrial fibrillation in accordance with the Heart Rhythm Society (HRS) 2017 AF expert consensus statement.

The cryoICE system in conjunction with an AtriClip® left atrial appendage (LAA) occlusion device will be used to perform the Cox-Maze III lesion set in this trial. Primary effectiveness is defined as freedom from Afib, atrial flutter, and/or atrial tachycardia lasting greater than 30 seconds and will be evaluated 12 months after the procedure. Long-term effectiveness will be evaluated three years post procedure.

"Cryothermal energy has been a mainstay of surgical ablation for a long time. The ICE-AFIB IDE trial is the first of its kind designed to assess the safety and sustained effectiveness of cryothermal ablation as a standalone energy source for surgical AF ablation," said Dr. Niv Ad, Director of Clinical Research at Washington Adventist Hospital and the national principal investigator of ICE-AFIB.

"While AtriCure's ABLATE™ clinical trial confirmed that the usage of the Isolator® Synergy™ Ablation System (radiofrequency ablation (heat)) when supplemented with select lesions created with cryothermal energy (cold) is an effective treatment for persistent and long-standing persistent Afib during cardiac surgery, the ICE-AFIB trial is a unique opportunity to generate systematic clinical evidence on the safety and effectiveness of cryosurgery for the treatment of such patients," said Michael Carrel, President and Chief Executive Officer of AtriCure. "The ICE-AFIB trial is yet another testament to AtriCure's commitment to and leadership in improving the lives of atrial fibrillation patients undergoing cardiac surgery."

The cryoICE ablation system was 510(k) cleared by the FDA in 2009 for the cryosurgical treatment of cardiac arrhythmias by freezing target tissues, which creates an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

About AtriCure, Inc.

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 33 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 and only medical device to receive FDA approval for the treatment of persistent Afib. AtriCure's AtriClip Left Atrial Appendage (LAA) Exclusion System products are the most widely sold LAA management devices worldwide, with more than 170,000 implanted to date. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

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