AtriCure Announces Completion of Patient Enrollment in the CONVERGE IDE Clinical Trial

August 28, 2018

Landmark study is the first prospective, randomized study comparing the Convergent approach to endocardial catheter ablation in persistent and long-standing persistent atrial fibrillation patients

MASON, Ohio--(BUSINESS WIRE)--Aug. 28, 2018-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments for atrial fibrillation (Afib) and left atrial appendage management, today announced it has completed enrollment of the full cohort of 153 patients in the CONVERGE IDE clinical trial.

The CONVERGE IDE trial is a landmark prospective, randomized trial underway in the United States comparing the Convergent approach to endocardial catheter ablation for patients with persistent or long-standing persistent Afib. The Convergent approach is a multi-disciplinary therapy in which a closed-chest epicardial ablation is performed by a surgeon, and then complemented by an endocardial catheter ablation performed by an electrophysiologist. Patients were enrolled at 25 sites across the United States, along with 2 sites in the United Kingdom.

“The full enrollment of the CONVERGE clinical trial is a significant milestone for AtriCure,” said Mike Carrel, President and Chief Executive Officer. “This study is the first of its kind, evaluating the multi-disciplinary Convergent approach against catheter ablation for patients who suffer from the most serious forms of Afib. We believe that once concluded, this study will be a meaningful step forward in demonstrating the safety and effectiveness of the Convergent approach.”

The CONVERGE study’s primary efficacy endpoint is for enrolled patients to be Afib, atrial tachycardia, and atrial flutter free, absent class I and III AADs except for a previously failed or intolerant class I or III anti-arrhythmic drugs, with no increase in dosage following the 3-month blanking period through the 12 months’ post procedure follow-up visit. The last patient follow-up is expected to be sometime in the third quarter of 2019, after which the company will submit final documentation to the Food and Drug Administration and seek a pre-market approval (PMA).

“The CONVERGE trial is an important step forward for the cardiology community in furthering available treatment options for Afib patients,” said Dr. David De Lurgio, principal investigator (PI) for the trial, and Director of Electrophysiology at Emory Heart and Vascular Center in Atlanta, GA. “This study is differentiated from other studies currently being conducted on the persistent and long-standing persistent population, because there is no time restriction on the duration of diagnosed Afib in the patients being studied. Patients with persistent and long-standing persistent Afib make up a very large percentage of the diagnosed population, and the trial is intended to study the safety and effectiveness of the Convergent approach for those patients that have limited other options for effective treatment.”

More information regarding the trial, including inclusion and exclusion criteria and primary and secondary outcome measures, can be found here: https://www.clinicaltrials.gov/ct2/show/NCT01984346

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 receiveFDA 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 150,000 implanted to date. 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. 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/fls as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We do not undertake to update our forward-looking statements. This document also includes forward-looking projected financial information that is based on current estimates and forecasts. Actual results could differ materially.

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