AtriCure Announces First Patient Enrolled in Stroke Feasibility Study

First U.S. clinical study to evaluate the safety of a novel epicardial-based left atrial appendage closure device for stroke prevention in atrial fibrillation patients.

WEST CHESTER, Ohio--(BUSINESS WIRE)--May 21, 2014-- AtriCure, Inc. (Nasdaq: ATRC), a leader in surgical solutions to treat atrial fibrillation (Afib), today announced the first patient enrolled in a feasibility study using the AtriClip® Left Atrial Appendage Exclusion System for stroke reduction in Afib patients unable to take anticoagulation. Dr. Marc Gerdisch, chief of cardiovascular and thoracic surgery at Franciscan St. Francis Health in Indianapolis, Indiana, performed the first procedure via a minimally invasive surgical approach. "We have used the AtriClip device for our at-risk patients undergoing open heart surgery since 2008, and it has performed exceptionally well," said Dr. Gerdisch. "With enrollment of this first stroke study patient, we have begun the process of providing atrial fibrillation patients at highest risk, the opportunity to eliminate the most common source of Afib-related strokes."

Patients with Afib are five times more likely to suffer a stroke compared with patients who have a normal heart rhythm. The higher risk of Afib-related stroke is believed to be related to the pooling of blood in a small muscular pouch within the left atria called the left atrial appendage (LAA). In Afib patients, the LAA has been shown to be the source of more than 90 percent of stroke-causing blood clots. [1] During Afib, blood flow out of the LAA is reduced, increasing the likelihood of clot formation. In some cases these clots travel from the heart to the brain blocking the blood supply. Afib-related strokes are typically much more severe and disabling than non-Afib strokes due to the size and location of clots.

Anticoagulant medications reduce the risk of stroke significantly although they carry a risk of severe bleeding. Other patients may be unable to maintain a therapeutic level of anticoagulation in their systems. This study will enroll Afib patients contraindicated to anticoagulation medication and as a result do not have a reasonable alternative available. No LAA closure devices have been approved for stroke prophylaxis in the United States to-date.

"Afib patients who are unable to take anticoagulation present a conundrum for cardiologists," according to Dr. J.D. Graham, the referring cardiologist for this case. "We need a reliable method to address their embolic risk, and the answer will come from controlled trials like this."

The Stroke Feasibility Study is being conducted under an Investigational Device Exemption (IDE). The Food & Drug Administration (FDA) previously cleared the AtriClip LAA Exclusion System for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures.

"This study is key to fulfilling our commitment to developing compelling Afib solutions that decrease the social and economic burden of atrial fibrillation," said Mike Carrel, chief executive officer of AtriCure. "We are enthusiastic that our first patient has been enrolled and that we are moving forward with this landmark trial, as we strive to improve the lives of patients with Afib."

Stroke Feasibility Study

The feasibility study is a prospective, single-arm, multi-center study for AtriClip Left Atrial Appendage Exclusion System delivered via a minimally invasive surgical procedure on a beating heart. Complete exclusion of the LAA is confirmed during the procedure using echo graphic imaging. The study will be conducted at seven leading centers in the United States, enrolling 30 patients.

The study objective is to evaluate the initial safety and efficacy of the AtriClip for stroke prevention in patients with non-valvular atrial fibrillation, in whom long-term oral anticoagulation therapy is medically contraindicated. For more information on this clinical study visit: www.clinicaltrials.gov. (CP 2011-2)
Pending the completion of this feasibility study, an IDE pivotal trial would be pursued to expand this study where the clinical data will be used to support a future indication for stroke prophylaxis in patients contraindicated to oral anticoagulation therapy.

About AtriClip

The AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. AtriCure received FDA 510(k) clearance for the AtriClip device in June 2010 based upon the successful results of the EXCLUDE trial (#G080095). In this study, complete exclusion of the LAA was confirmed in 98.4 percent of patients at three months post procedure by a CT scan.

With more than 30,000 devices implanted, the AtriClip LAA Exclusion System is the most widely implanted LAA exclusion device in the world.

About AtriCure

AtriCure, Inc. is a medical device company providing innovative atrial fibrillation (Afib) solutions designed to produce superior outcomes that reduce the economic and social burden of atrial fibrillation. AtriCure's Synergy Ablation System is the first and only device approved for the treatment of Persistent and Longstanding Persistent forms of Afib in patients undergoing certain open concomitant procedures. AtriCure's AtriClip Left Atrial Appendage (LAA) exclusion device is the most widely implanted device for LAA management worldwide. The company believes cardiothoracic surgeons are adopting its ablation and LAA management devices for the treatment of Afib and reduction of Afib related complications such as stroke. Afib affects more than 5.5 million people worldwide.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements that address activities, events or developments that AtriCure expects, believes or anticipates will or may occur in the future, such as earnings

estimates (including projections and guidance), other predictions of financial performance, launches by AtriCure of new products and market acceptance of AtriCure's products. Forward-looking statements are based on AtriCure's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond AtriCure's control. These risks and uncertainties include the rate and degree of market acceptance of AtriCure's products, AtriCure's ability to develop and market new and enhanced products, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products, the timing of and ability to obtain reimbursement of procedures utilizing AtriCure's products, AtriCure's ability to consummate acquisitions or, if consummated, to successfully integrate acquired businesses into AtriCure's operations, AtriCure's ability to recognize the benefits of acquisitions, including potential synergies and cost savings, failure of an acquisition or acquired company to achieve its plans and objectives generally, risk that proposed or consummated acquisitions may disrupt operations or pose difficulties in employee retention or otherwise affect financial or operating results, competition from existing and new products and procedures or AtriCure's ability to effectively react to other risks and uncertainties described from time to time in AtriCure's SEC filings, such as fluctuation of quarterly financial results, reliance on third party manufacturers and suppliers, litigation or other proceedings, government regulation and stock price volatility. AtriCure does not guarantee any forward-looking statement, and actual results may differ materially from those projected. AtriCureundertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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[1] Manning WJ. Atrial fibrillation, transesophageal echo, electrical cardioversion, and anticoagulation. *Clin Cardiol.* 1995; 18: 58,114 .

[2] Lloyd-Jones D, Adams RJ, Brown TM, et al. Heart Disease and Stroke Statistics—2010 Update: a report from theAmerican Heart Association*. Circulation*. 2010;121:e91.

[3] Coyne KS, Paramore C, Grandy S, Mercader M, Reynolds M, Zimetbaum P. Assessing the direct costs of treating nonvalvular atrial fibrillation in the United States. *Value Health*. 2006 Sep–Oct;9(5):348–56.

Source: AtriCure, Inc.