AtriCure Launches Three-Year Post-Approval Study For the Surgical Correction of Atrial Fibrillation

The Associated Press

WEST CHESTER, Ohio--(BUSINESS WIRE)--Sep 12, 2012--AtriCure, Inc. (NASDAQ: ATRC), the leader in surgical ablation for the treatment of Atrial Fibrillation, has announced FDA approval of the ABLATE Post Approval Study (PAS). This landmark three-year, 350 patient study is a follow-up to the company's December 14, 2011 FDA approval of the AtriCure Synergy Ablation System for the surgical treatment of Atrial Fibrillation (AF). AtriCure is the first and only surgical company with a specific, on label indication for AF. The PAS study is intended to build additional evidence on the safety, efficacy and long-term durability of the Maze IV concomitant treatment for AF using AtriCure's proprietary surgical devices.

The initial FDA approval study, ABLATE, reported 84 percent of patients free from AF at six months following Maze IV treatment and 75 percent of patients free of AF at a mean follow-up of 22 months when assessed by 48-hour Holter monitors. The Maze IV procedure is normally performed at the time of a primary open heart procedure where access to the heart is routinely established.

The ABLATE and PAS studies focus on the most difficult to treat, chronic forms of AF known clinically as "non-paroxysmal AF." The chronic AF patient group represents roughly half of the diagnosed patient population and has been extremely challenging to manage with conventional medical therapy or catheter ablation.

According to Patrick McCarthy, MD,* Director of the Bluhm Cardiovascular Institute at Northwestern University Feinberg School of Medicine and Chair of the PAS Executive Committee, "The ABLATE Post Approval Study represents an important study which will provide the evidence to validate the treatment of these underserved patients with intractable forms of AF," he says. "This trial represents the most comprehensive experience for any treatment option for atrial fibrillation, and we're looking forward to this significant study designed to treat patients with this life-threatening condition." The company's founder, Michael Hooven, is optimistic about the FDA approval and the PAS. "Receiving the first and only FDA approval for the surgical treatment of Atrial Fibrillation was a major milestone for AtriCure. We are now able to fulfill our mission of improving patient outcomes by offering a standardized surgeon training program focused on the Maze IV procedure. Our data suggests that currently only 3 in 10 cardiac surgery patients with an AF diagnosis receive an AF procedure and only 1 in 10 receive a complete Maze IV procedure. We expect the PAS study will provide additional compelling evidence of the benefits of the AtriCure Maze IV procedure and be a catalyst for making it the standard of care." Concurrently with the post-approval study, AtriCure is sponsoring an extensive Maze IV training program for cardiovascular surgeons. This course was developed by recognized leaders in the field of surgical ablation

and is recognized by the Society of Thoracic Surgeons as an Endorsed Industry Education Program. For more information about this course, visit targetaf.com.

About AtriCure, Inc. AtriCure, Inc. is a leader in medical device development, manufacturing and sales of innovative cardiac surgical ablation systems designed for the treatment of AF and for the exclusion of the left atrial appendage. AF affects more than 2 million people in the United States and is responsible for 15 percent of strokes. It is estimated that by 2050 more than 12 million individuals will have a form of AF. For more information regarding AtriCure, visit www.atricure.com The FDA has not cleared or approved certain AtriCure products for the treatment of AF or a reduction in the risk of stroke. 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, 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, 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. AtriCure undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

*Dr. McCarthy has been reimbursed by AtriCure for limited travel and related expenses related to his involvement in the ABLATE AF PAS clinical trial. MKT-1639A-G
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