AtriCure's AtriClip(TM) System Receives FDA 510(k) Clearance

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WEST CHESTER, Ohio, Jun 14, 2010 (BUSINESS WIRE) --AtriCure, Inc. (Nasdaq: ATRC), a medical device company and a leader in cardiac surgical ablation systems, today announced that it received clearance from the FDA for its AtriClip Gillinov-Cosgrove Left Atrial Appendage Exclusion system. The AtriClip system is designed to safely and effectively exclude the left atrial appendage. Initial launch in the United States is anticipated to begin later this month with full commercial release planned during the third quarter of 2010.

"Clearance of the AtriClip system in the United States represents a major product and clinical milestone for AtriCure," said David J. Drachman, President and Chief Executive Officer. "We believe that the AtriClip system provides a safe and efficient method to exclude the left atrial appendage. This key innovation represents a large and exciting new growth platform and demonstrates our steadfast commitment to developing market leading technologies to meet the needs of patients and physicians."

About the Left Atrial Appendage and the AtriClip System

The AtriClip system includes a clip device that is designed to exclude the left atrial appendage, a hollow sac-like structure attached to the heart's left atrium. The left atrial appendage has internal peaks and valleys, or trabeculations. During AF, stagnant blood pools in the trabeculations of the left atrial appendage and is known to form clots that can migrate to other parts of the body. The AtriClip is designed to be implanted from the outside of the heart, avoiding contact with circulating blood and eliminating blood flow between the left atrial appendage and the atria. The AtriClip system has been cleared by the FDA for occlusion of the left atrial appendage, under direct visualization, in conjunction with other open-heart cardiac procedures.

About AtriCure, Inc.

AtriCure, Inc. is a medical device company and a leader in developing, manufacturing and selling innovative cardiac surgical ablation systems designed to create precise lesions, or scars, in cardiac, or heart, tissue and systems for the exclusion of the left atrial appendage. Medical journals have described the adoption by leading cardiothoracic surgeons of the AtriCure Isolator(R) bipolar ablation system as a treatment alternative during open-heart surgical procedures to create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart. Additionally, medical journals and leading cardiothoracic surgeons have described the AtriCure Isolatorsystem as a promising treatment alternative for patients who may be candidates for sole-therapy minimally invasive procedures. AF affects more than 5.5 million people worldwide and predisposes them to a five-fold increased risk of stroke. The FDA has cleared the AtriCure Isolator system and AtriCure's multifunctional pen and Coolrail™ linear ablation device, for the ablation, or destruction, of cardiac tissue during surgical procedures. Additionally, the FDA has cleared AtriCure's multifunctional pen for temporary pacing, sensing, stimulating and recording during the evaluation of cardiac arrhythmias and AtriCure's Cryo1 system for the cryosurgical treatment of cardiac arrhythmias. To date, the FDA has not cleared or approved AtriCure's products for the treatment of AF.

SOURCE: AtriCure, Inc.

AtriCure, Inc.
Julie A. Piton, Vice President and Chief Financial Officer, 513-755-4561
jpiton@atricure.com