Cardiovascular Systems Completes PMA Submission of Orbital Atherectomy System for Coronary Artery Disease Treatment

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Mar 15, 2013--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), announced today that it has submitted its Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for its orbital atherectomy system, used to treat calcified coronary arteries.

The completed PMA application marks another major coronary milestone for CSI, following the release of ORBIT II pivotal trial results at the recent 2013 American College of Cardiology (ACC) conference. CSI's technology produced clinical outcomes that exceeded the trial's two primary safety and efficacy endpoints by a significant margin—within one of the most challenging patient populations.

"Coronary arterial calcium is a vastly underestimated problem in medicine today, and there is a pressing need for a solution," said David L. Martin, president and CEO of Cardiovascular Systems. "The ORBIT II results we shared at ACC show that our orbital atherectomy technology may be a viable treatment option for calcified coronary arteries. We look forward to working with the FDA on a potential coronary indication for this most challenging, underserved patient population." The company completed ORBIT II enrollment of 443 patients at 49 U.S. medical centers in November 2012. ORBIT II is evaluating the safety and effectiveness of the company's orbital atherectomy technology in treating patients with severely calcified coronary lesions. This is the first Investigational Device Exemption study in history to evaluate this problematic subset of patients. At ACC, Dr. Jeffrey Chambers of Metropolitan Heart and Vascular Institute, Minneapolis, presented data that showed a 30-day freedom from MACE (major adverse cardiac events) rate of 89.8 percent and procedural success of 89.1 percent (including in-hospital MACE).

According to estimates, moderate to severe arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention. Moderate-to-severe calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and MACE. Coronary approval would open up a large, underserved market opportunity for CSI, estimated to exceed $1.5 billion annually in the United States.

The FDA agreed to a modular PMA process that allowed CSI to submit the first two modules covering preclinical data and manufacturing/quality systems, while still collecting, compiling and analyzing the clinical data. CSI has now submitted the third and final PMA application module, as well as responses to FDA comments on the first two modules, which were submitted in late 2012.

About Coronary Artery Disease
Coronary Artery Disease (CAD) is a life-threatening condition and leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or several of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. CAD affects an estimated 16.8 million people in the United States and is the most common form of heart disease. Heart disease claims more than 600,000 lives, or 1 in 4 Americans, in the United States each year.

About Cardiovascular Systems, Inc.
Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company's Orbital Atherectomy Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback Orbital Atherectomy System in August 2007. To date, over 100,000 of CSI's devices have been sold to leading institutions across the United States. The coronary system is limited by federal law to investigational use and is currently not commercially available in the United States.

For more information, visit the company's website at www.csi360.com.