Cardiovascular Systems' Orbital Atherectomy Technology Highlighted at ACC Innovations Forum

The Associated Press

ST. PAUL, Minn., & SAN FRANCISCO--(BUSINESS WIRE)--Mar 12, 2013--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), was featured as part of the "Innovation and Technology Adoption" presentation during the Innovations Educational Forum at the 2013 American College of Cardiology (ACC) conference in San Francisco. Dr. Glen Nelson, CSI's Chairman of the Board, moderated the session.

Data presented by Dr. William Gray, Director of Endovascular Services, Columbia University, New York, N.Y., illustrated that calcified lesions are underestimated, challenging to treat and lead to increased complications. The presentation demonstrated the effectiveness of CSI's peripheral orbital atherectomy system (OAS) in treating calcified lesions and its ability to change vessel compliance—minimizing vascular injury that may lead to restenosis.

Additionally, follow-up on prior CSI studies shared during the forum showed that CSI's OAS has consistent procedural outcomes, low complications and long-term durability in treating calcified lesions.

Also presented at ACC were pivotal trial results from CSI's ORBIT II study of patients with severely calcified coronary arteries. ORBIT II is evaluating the safety and effectiveness of the company's OAS in treating one of the most challenging patient populations. At 30 days, patient outcomes exceeded the study's primary safety and efficacy endpoint targets by a significant margin. Moderate to severe arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention, according to estimates.

Additionally, 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 major adverse coronary events (MACE). A coronary approval would open up a large, underserved market opportunity for CSI, estimated to exceed $1.5 billion annually in the United States.

CSI completed ORBIT II enrollment of 443 patients at 49 U.S. medical centers in November 2012. CSI is targeting the end of March 2013 to submit its Premarket Approval application to the Food and Drug Administration.

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. CSI has completed its ORBIT II Investigational Device Exemption clinical trial to evaluate the safety and effectiveness of its orbital technology in treating coronary arteries. 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.