CSI Presents Three-Year Orbit I Coronary Data at CRT 2013

The Associated Press

ST. PAUL, Minn. & WASHINGTON--(BUSINESS WIRE)--Feb 25, 2013--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), today presented three-year data from its ORBIT I feasibility study of calcified coronary lesions during a poster session at the 2013 Cardiovascular Research Technologies (CRT) conference.

The ORBIT I study evaluated the safety of CSI's orbital atherectomy system as a treatment for mild to severely calcified coronary arteries. Results from the 50-patient feasibility trial formed the basis for the ORBIT II pivotal trial. This three year feasibility data shows that using CSI's technology to treat calcified coronary arteries before stenting achieved not only early procedural success but also positive long-term outcomes.

"This case series demonstrates that CSI's system can safely modify calcified lesions and facilitate stent delivery in this subset of difficult-to-treat patients," said presenter Dr. Stevan Himmelstein, Baptist Memorial Hospital-Desoto, Memphis, Tenn. "Coronary artery disease, or CAD, is the leading cause of death for men and women in the United States. To have a potential solution for this pressing problem is encouraging." It is estimated that moderate to severe arterial calcium is present in nearly 40 percent of patients treated with interventional therapies. Calcium can lead to poor outcomes and higher treatment costs in coronary intervention when traditional therapies are used, including a significantly higher occurrence of death and major adverse coronary events.

The ORBIT I study consisted of 50 patients enrolled at two sites in India from May to June 2008. All subjects had at least one calcified coronary lesion with stenosis between 50 and 100 percent. 33 of the 50 patients were enrolled at one of the two sites and were followed for three years post procedure. The evaluated safety endpoint was major adverse cardiac event (MACE) rates.

Results show: David L. Martin, CSI president and chief executive officer, said, "Based on the results from our ORBIT I clinical study, demonstrating the safety in treating severely calcified coronary lesions our orbital platform technology may be well suited for the removal of calcified plaque in coronary arteries. Our pivotal 443-patient ORBIT II PMA clinical study has recently concluded and we are nearing completion of an FDA submission to secure a coronary indication for our technology." CSI completed enrollment in the ORBIT II trial in November of 2012. ORBIT II is CSI's pivotal coronary IDE trial studying this problematic subset of patients. CSI is targeting the end of this quarter to submit its Premarket Approval (PMA) package to the FDA.

CSI Booth at CRT: Feb. 25 – 26 Visit CSI at booth #112, 8 a.m. – 5 p.m. today and 9

a.m. – 2 p.m. Tuesday, Feb. 26, to meet the company's calcium experts and learn more about CSI's unique orbital technology.

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 also commenced 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.

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