Cardiovascular Systems to Present Three-Year Orbit I Coronary Data at 2013 Cardiovascular Research Technologies Conference

The Associated Press

ST. PAUL, Minn., & WASHINGTON--(BUSINESS WIRE)--Feb 19, 2013--Cardiovascular Systems, Inc. (CSI) (Nasdaq:CSII), will present three-year data from its ORBIT I study of coronary artery disease (CAD) in a poster session at the 2013 Cardiovascular Research Technologies (CRT) conference in Washington, D.C., Feb. 23-26, 2013.

The ORBIT I study evaluated the safety and efficacy of CSI's orbital atherectomy system as a treatment for mild to severely calcified coronary arteries. Results from the 50-patient feasibility trial show that using CSI's technology to treat calcified coronary arteries before stenting achieved procedural success and compelling long-term outcomes.

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 was CSI's first trial to collect clinical data on this subset of patients – people with calcified coronary arteries who were excluded from the majority of clinical trials previously conducted.

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.

Poster Session: Feb. 25 WHAT: Dr. Stevan Himmelstein, Baptist Memorial Hospital-Desoto, Memphis, Tenn., will present "Orbital Atherectomy System in Treating Calcified Coronary Lesions: First in Man Assessment—Three-Year Follow Up (ORBIT I Trial)" in a poster session.

CSI Booth at CRT: Feb. 24 – 26 Visit CSI at booth #112 11 a.m. – 7 p.m. Sunday, Feb. 24; 8 a.m. – 5 p.m. Monday, Feb. 25; and 9 a.m. – 2 p.m. Tuesday, Feb. 26, to meet the company's calcium experts and learn more about its 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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