Cardiovascular Systems Releasing Late-Breaking Confirm Series Data at ISET Conference

The Associated Press

ST. PAUL, Minn. & MIAMI--(BUSINESS WIRE)--Jan 16, 2013--Cardiovascular Systems, Inc. (CSI) (Nasdaq: CSII), will present late-breaking data from its CONFIRM study series, an oral abstract from its CALCIUM study, and conduct other educational and poster sessions at the 25 th annual International Symposium on Endovascular Therapy (ISET) conference in Miami, Jan. 19–23, 2013.

The CONFIRM study series evaluated the safety and procedural effectiveness of CSI's orbital atherectomy system as a treatment for peripheral arterial disease (PAD) —above- and below-the-knee lesions— in a real world population of patients (no exclusions). Eighty-one percent of the lesions had severe or moderate calcification—historically considered a difficult patient population to treat. CONFIRM, like other studies in CSI's growing body of clinical research, is aimed at providing physicians with scientific data to make sound treatment decisions.

Arterial calcification is a common, underdiagnosed condition with complicating factors—including a higher frequency of dissections and perforations—that pose a challenge for physicians treating PAD. Calcified lesions are estimated to be present in approximately 65 percent of the people treated annually for PAD and are more prevalent in distal vessels below the knee.

ISET Late-Breaking Trial Results Presentation: Jan. 21 WHAT: Dr. Tony Das, Cardiology and Interventional Vascular Associates, Dallas, Texas, a significant contributor to the execution and analysis of the CONFIRM series, will present the late-breaking results.

The CONFIRM series consisted of three real-world studies, using a common protocol, from 2009 to 2011 that used CSI's orbital atherectomy systems to treat more than 3,100 patients (4,700 lesions), 82 percent with moderate to severe calcium. CSI's orbital atherectomy system is minimally invasive and indicated for use as therapy in patients with PAD.

Additional CSI Presentations and Sessions: Concurrent Session I: Abstracts and Late-Breaking Trials: Jan. 21 WHAT: Dr. Jonathan Ellichman, Southern Cardiovascular, Memphis, Tenn., will share Orbital Atherectomy and Balloon Angioplasty vs. Angioplasty Alone in Critical Limb Ischemia: Results of the CALCIUM 360° Trial in an oral presentation.

CSIQ Educational Session: Jan. 21 WHAT: As part of its medical education program, CSIQ, CSI will host a hands-on cadaver lab for physicians who want to learn antegrade and retrograde tibial access.

Poster Sessions: Jan. 22 WHAT: Dr. Barry Weinstock, Mid-Florida Cardiology Specialists, Orlando, Fla., and Dr. Raymond Dattilo (presenter), St. Francis Health Center, Topeka, Kan., will present Cost Consequences of Orbital Atherectomy Plus Angioplasty vs. Angioplasty Alone for Treatment of Calcified Femoropopliteal Lesions in a poster session.

CSI Booth at ISET: Jan 21 – 23 Visit CSI at booth #406 7:30 a.m. – 4:30 p.m. Monday, Jan. 21, through Wednesday, Jan. 23, to meet the company's calcium experts and learn more about its unique orbital technology.

About Peripheral Arterial Disease
PAD is a life-threatening condition where a fatty material called plaque builds up on the inside walls of the blood vessels that carry blood from the heart to legs and arms. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow to the legs. The risk of PAD increases if a person has one or several of the following: high blood pressure, abnormal cholesterol levels, diabetes, or personal history of heart disease, heart attack or stroke. PAD affects an estimated 8-12 million people in the United States. The disease prevalence increases with age and 12-20 percent of Americans age 65 and older suffer from PAD symptoms. As the U.S. population ages, the prevalence range could reach 16 million in those age 65 and older and 19 million overall by 2050.

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, nearly 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 [1].

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