CSI Presents Late-Breaking Data at ISET 2013

The Associated Press

ST. PAUL, Minn. & MIAMI--(BUSINESS WIRE)--Jan 23, 2013--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), today announced CONFIRM study series data presented at the 2013 International Symposium on Endovascular Therapy (ISET). Results show that CSI's minimally invasive orbital atherectomy system is an effective treatment for peripheral arterial disease (PAD). CSI's technology protects healthy vessel tissue while removing even the most difficult-to-treat plaque throughout the leg with fewer complications. The study titled "Procedural Effectiveness of Orbital Technology in More Than 3,100 Patients with Infra-inguinal Disease: Results from the CONFIRM Series" was part of a late-breaking presentation at ISET.

"The 3,000-plus real-world patients studied in the CONFIRM series shows that CSI's orbital atherectomy system safely and effectively treats moderate-to-severely calcified lesions," said presenter Dr. Tony Das, Cardiology and Interventional Associates, Dallas, Texas. "Orbital atherectomy led to low bail-out-stent usage, low adverse procedural-event rates and improved lesion compliance. Additionally, smaller randomized studies point to improved vessel durability and long-term outcomes—both of which are a first for atherectomy trials in the peripheral vascular space." The prevalence of arterial calcium is vastly underestimated in medicine today. Calcium, even if it isn't visible through angiography, is present in about 65 percent of the 2.5 million people diagnosed annually with PAD. Moreover, calcium leads to poor outcomes and higher treatment costs when traditional balloon and stent therapies are used—including dissection, vessel wall trauma and stent fracture.

David L. Martin, CSI president and chief executive officer said: "CONFIRM reinforces the effectiveness of CSI's orbital atherectomy in treating 'real world' patients. The dataset presented today is the largest ever for PAD, and the CONFIRM study series shows consistent, repeatable results across numerous interventional physicians. CONFIRM gives physicians confidence that our technology is an effective and safe PAD treatment for patients." The CONFIRM series consisted of three studies that enrolled more than 3,100 patients with 4,700 lesions at 350 sites across the United States from 2009 to 2011. A majority of the lesions had moderate to severe calcium. During the initial study, physicians treated lesions to maximize the luminal gain, while the second and third study focused on removing calcium to change vessel compliance. Each study utilized a progressively smaller crown which reduced slow flow, vessel closure and spasms.

Data shows that vessel preparation with CSI's orbital atherectomy system enables low-pressure adjunctive balloon angioplasty across the studies, with low procedural events and bail-out stents—which preserve treatment options in the future.

Overall Procedural Outcomes: CALCIUM 360° Study 12-Month Results Also presented at ISET: "Comparison of Orbital Atherectomy Plus Balloon Angioplasty vs.

Balloon Angioplasty Alone in Patients With Critical Limb Ischemia: Results of the CALCIUM 360 Randomized Pilot Trial," by Dr. Jonathan Ellichman, Southern Cardiovascular, Memphis, Tenn. Results demonstrate that orbital atherectomy treatment with low-pressure percutaneous transluminal angioplasty (PTA) safely restores flow in patients with critical limb ischemia and reduces major serious adverse events, compared to PTA alone.

At 12 months, CSI's technology provided superior outcomes: CALCIUM 360° is a prospective, multi-center randomized study that compared treatment of below-the-knee lesions with orbital atherectomy versus PTA. All 50 patients had critical limb ischemia (CLI) and calcified lesions. These conditions are challenging to treat in the small arteries below the knees and often a precursor to amputation.

CSI Poster Session at ISET Dr. Barry Weinstock, Mid-Florida Cardiology Specialists, Orlando, Fla., and Dr. Raymond Dattilo (presenter), St. Francis Health Center, Topeka, Kan., presented Cost Consequences of Orbital Atherectomy Plus Angioplasty vs. Angioplasty Alone for Treatment of Calcified Femoropopliteal Lesions in a poster session at ISET.

Data shows that orbital atherectomy plus balloon angioplasty has a significantly lower average stenosis rate, exhibiting compelling short- and longer-term health and economic data for the use of atherectomy in the treatment of calcified femoropopliteal lesions.

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.

Product Disclosure The Stealth 360° ® PAD System, Diamondback 360 ® PAD System and Predator 360 ® PAD System are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The systems are contraindicated for use in coronary arteries, bypass grafts, stents or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

CONTACT: Cardiovascular Systems, Inc.

Investor Relations, 651-259-2800 investorrelations@csi360.com or Sarah Wozniak, 651-259-1636 swozniak@csi360.com or Padilla Speer Beardsley Inc.

Matt Sullivan, 612-455-1709 msullivan@padillaspeer.com or Dave Folkens, 612-455-1741 dfolkens@padillaspeer.com KEYWORD: UNITED STATES NORTH AMERICA FLORIDA MINNESOTA INDUSTRY KEYWORD: SURGERY HEALTH CARDIOLOGY CLINICAL TRIALS HOSPITALS MEDICAL DEVICES MANAGED CARE SOURCE: Cardiovascular Systems, Inc. Copyright Business Wire 2013 PUB: 01/23/2013 04:59 PM/DISC: 01/23/2013 04:59 PM http://www.businesswire.com/news/home/20130123006525/