# Cardiovascular Systems Completes Patient Enrollment in Orbit II Coronary Trial

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Nov 27, 2012--Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), today announced it has completed enrollment in its ORBIT II clinical trial, enrolling 443 patients. ORBIT II is evaluating the safety and effectiveness of the company's orbital atherectomy technology in treating severely calcified coronary arteries. It is estimated that moderate to severe arterial calcium is present in nearly 40 percent of those treated annually for coronary artery disease (CAD). ORBIT II is the first premarket approval (PMA) trial designed to study these difficult-to-treat patients.

"Completing ORBIT II enrollment is a significant milestone in our efforts to secure a coronary indication to treat arterial calcium—a vastly underestimated problem in medicine today," said David L. Martin, CSI president and chief executive officer. "At TCT this year, Dr. Philippe Genereux presented new data proving, with statistical significance, that patients with moderate to severe calcium were more likely to die, and have major adverse coronary events–results Dr. Genereux described as 'shocking.'" The data presented at TCT by Dr. Genereux, Director of the Angiographic Core Laboratory at the Cardiovascular Research Foundation (CRF), was from 14 randomized trials and included 11,651 treated with drug-eluting stents. While almost all of the studies were designed to exclude patients with moderate to severe calcium, nearly 21 percent of the patients enrolled actually had that level of calcium as confirmed by an independent angiographic core laboratory. Results from this patient subset showed statistically higher rates of death and major adverse cardiac events (MACE), including myocardial infarction, definitive stent thrombosis or ischemic target lesion revascularization, than patients with no or mild calcium.

Dr. Jeffrey Chambers, interventional cardiologist with Metropolitan Cardiovascular Consultants, Minneapolis, and Principal Investigator for the ORBIT II study, said, "Despite advanced stent technology, moderate to severe calcification remains a real challenge for interventional cardiologists, and new therapeutic approaches are needed. Based on promising results in treating severely calcified coronary arteries in the ORBIT I study, CSI's orbital technology may be well suited for removing calcified plaque in coronary lesions. I look forward to seeing the results from ORBIT II and I'm hopeful that we will have a new therapy in the near future for these difficult-to-treat patients." CSI received FDA investigational device exemption (IDE) approval for the ORBIT II study in April 2010, and more than 45 U.S. medical centers enrolled patients. The primary endpoints of ORBIT II are based on a 30-day patient follow-up post procedure. Of the 443 patients enrolled in ORBIT II, 343 were treated with CSI's original pneumatic orbital atherectomy system (OAS) and 100 with the company's new electric OAS. The new electric coronary OAS offers a simpler design that gives physicians complete control of device operation, with minimal set up time. CSI and the FDA agreed to a modular PMA submission. To date, modules 1

(preclinical) and 2 (manufacturing/system quality) have been submitted to the agency and are currently under review. The company's PMA will be final on submission of module 3 which includes ORBIT II clinical data and proposed labeling. CSI anticipates that this will occur in early 2013. A coronary application would open up a large, underserved market opportunity for CSI, estimated to exceed $1.5 billion annually.

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 addresses 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.

Safe Harbor Certain statements in this news release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements in this press release regarding (i) CSI's potential coronary application; (ii) CSI's clinical trials; (iii) the timing of the company's PMA becoming final; and (iv) the large, underserved market opportunity for CSI that a coronary application of CSI's orbital technology would open up and the $1.5 billion estimate of such market, are forward-looking statements.

These statements involve risks and uncertainties which could cause results to differ materially from those projected, including but not limited to the reluctance of physicians to accept new products; the effectiveness of CSI's orbital technology; actual clinical trial results; the impact of competitive products and pricing; FDA clearances and approvals; approval of products for reimbursement and the level of reimbursement; general economic conditions and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. CSI encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this release. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, CSI's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this release. The forward-looking statements made in this release are made only as of the date of this release, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.

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.

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