

## Cardiovascular Systems Receives Conditional IDE Approval for ORBIT II Coronary Clinical Trial

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Pivotal Study to Evaluate Clinical Benefits of Treating Calcified Coronary Lesions with the Diamondback 360(R) System

ST. PAUL, Minn.--(BUSINESS WIRE)--January 14, 2010--

Cardiovascular Systems, Inc. (CSI) (Nasdaq:CSII), has received Food and Drug Administration (FDA) conditional Investigational Device Exemption (IDE) approval to evaluate the safety and effectiveness of its Diamondback 360(R) System in the treatment of calcified coronary lesions. With this conditional approval, CSI is authorized to begin its pivotal trial, ORBIT II, in early 2010 and initially enroll up to 100 patients at as many as 50 U.S. sites. Dr. Jeffrey Chambers, an interventional cardiologist with Metropolitan Cardiovascular Consultants Minneapolis, is the principal investigator for ORBIT II. The Diamondback 360[deg] is a minimally invasive catheter, which received FDA 510(k) marketing clearance in 2007 for the treatment of peripheral arterial disease.

"The U.S. market for coronary interventions is currently estimated at more than \$4 billion, representing 1.3 million procedures each year," said David L. Martin, president and CEO of Cardiovascular Systems. "A complementary tool to stents and angioplasty, we expect our Diamondback 360[deg] to play a significant role in this market by removing the calcified or fibrocalcific disease to increase the effectiveness of the other therapies. We are optimistic that the success of the Diamondback 360[deg] in treating peripheral arterial disease -- as confirmed in our landmark OASIS study and in more than 20,000 patients to date -- can be repeated in the treatment of coronary disease."

In 2008, CSI completed the first in-human ORBIT I coronary trial, a feasibility study which enrolled 50 patients in India. The Diamondback 360[deg] was shown successful in 98 percent of patients, and the acute procedural success rate was 94 percent. These results met the company's safety and efficacy endpoints and were among the data the FDA considered in granting conditional IDE approval.

"We have seen the advantages of using the Diamondback 360[deg] in removing calcified coronary plaque prior to using stents or angioplasty " said Dr. Chambers. "In the feasibility study, acute procedural outcomes were positive, and we believe the use of the device also may contribute to improved long-term outcomes in patients with difficult-to-treat disease. We look forward to expanding our understanding of this platform technology for a coronary indication."

The Diamondback 360[deg] catheter has a diamond-coated crown and unique orbital mechanism of action, ideally suited for removing calcific and fibrocalcific plaque. The coronary platform has been designed for ease-of-use, short procedure times and a minimized risk of complications by using a low-profile catheter, a turbine-powered controller and the proprietary ViperWire(TM) Guide Wire.

CSI received FDA 510(k) marketing clearance for the Diamondback 360[deg] as a PAD therapy on the basis of data from its OASIS study, the first-ever prospective study evaluating a plaque removal system, which enrolled 124 patients at 20 sites. Acute outcomes demonstrated that the Diamondback 360[deg] device is safe and effective. Six-month results showed no major amputations, and 97.5 percent of patients required no reintervention. Recently announced follow up on 64 patients demonstrated the long-term durability of treatment with the Diamondback 360[deg], with a 100-percent limb salvage rate maintained and freedom from reintervention in 86.4 percent of patients after two years.

#### 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 intended to enjoy 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 ability to play a significant role in the market for coronary interventions; (ii) the anticipated improvement in outcomes, especially in patients with calcified or fibrocalcific disease with the Diamondback 360[deg]; and (iii) repeating CSI's success in treating PAD in treatment of coronary disease 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 potential for unanticipated delays in enrolling medical centers and patients for studies; new data or events that may disrupt plans for these studies; unexpected results or clinical outcomes in the ORBIT II trial and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K. 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.

#### About Cardiovascular Systems, Inc.

Cardiovascular Systems Inc., (CSI) (Nasdaq: CSII) based in St. Paul, Minn., is a medical device company focused on providing clinically proven, safe and effective solutions for vascular disease. The company's Diamondback 360(R) PAD System removes calcified and fibrotic plaque in small and large peripheral vessels, and addresses many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. In August 2007, the U.S.

FDA granted 510(k) clearance for the use of the Diamondback 360[deg] as a therapy for PAD (peripheral arterial disease), and CSI commenced a U.S. product launch in September 2007. Since then, more than 20,000 procedures have been performed using the system. For more information visit the company's Web site at [www.csi360.com](http://www.csi360.com).

#### Product Disclosure

The Diamondback 360(R) PAD System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The system is 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.