



CARDIOVASCULAR SYSTEMS RECEIVES UNCONDITIONAL FDA APPROVAL FOR ORBIT II CORONARY CLINICAL TRIAL

Pivotal Study Will Evaluate Clinical Benefits of Treating Calcified Coronary Lesions with Diamondback 360[®] System

St. Paul, Minn., April 27, 2010 – Cardiovascular Systems, Inc. (CSI) (Nasdaq: CSII), has received Food and Drug Administration unconditional Investigational Device Exemption (IDE) approval, allowing the company to proceed with ORBIT II, a pivotal trial to evaluate the safety and effectiveness of CSI's Diamondback 360[®] System in the coronary arteries. CSI received conditional IDE approval for the ORBIT II study in January 2010. The pivotal trial will initially enroll up to 100 patients at as many as 50 U.S. sites, with the potential to enroll up to 429 patients. Dr. Jeffrey Chambers, an interventional cardiologist with Metropolitan Cardiovascular Consultants, Minneapolis, is the principal investigator.

The Diamondback 360[°] is designed to be well suited for removing calcific and fibrocalcific plaque in coronary lesions. The system uses a diamond-coated crown with a unique orbital mechanism of action to sand and remove hardened plaque, which may facilitate more effective stent placement and restoration of blood flow in the coronary arteries. The orbital action also allows continuous saline and blood flow through the lesion, which may be advantageous during treatment.

"The unconditional FDA IDE approval continues CSI's progress toward regulatory approval for a coronary application and potential significant market expansion for our product technology," said David L. Martin, president and CEO of Cardiovascular Systems. "We are optimistic the ORBIT II study will reinforce the safety and effectiveness of removing plaque using the Diamondback 360[°] System, as already shown in our ORBIT I coronary feasibility study of 50 subjects and in the treatment of more than 25,000 patients to date with peripheral arterial disease (PAD)."

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

Dr. Chambers said, "Coronary arterial disease is the most common form of heart disease in the United States, affecting more than 16 million people. After the successes of the ORBIT I study, we are eager to expand the number of coronary patients treated with the Diamondback 360[°], and acquire acute and long-term data. We believe the unique features of the Diamondback 360[°] are designed specifically to remove calcified plaque in coronary arteries to facilitate stent placement."

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) the number of patients and sites that will be involved in the ORBIT II trial; (ii) CSI's progress toward regulatory approval for a coronary application; and (iii) CSI's optimism about the outcomes in a coronary application through the ORBIT II study, 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

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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 interventional solutions for vascular disease. The company's Diamondback 360[®] 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[°] as a therapy for PAD (peripheral arterial disease), and CSI commenced a U.S. product launch in September 2007. Since then, more than 25,000 procedures have been performed using the system. For more information visit the company's Web site at www.csi360.com.

Product Disclosure

The Diamondback 360[®] 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.

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