

CSI Reports Two-Year Data Showing Durable Outcomes in Patients Treated with Diamondback 360° PAD System

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Data Discussed at TCT 2009

Sept. 22, 2009 – Two-year follow-up of patients in the first-ever prospective, multi-center clinical trial evaluating a plaque removal product show promising results after treatment with the Diamondback 360°[®] PAD System, a minimally invasive catheter system that removes hardened plaque to restore blood flow in arteries. Dr. Barry Weinstock, Mid-Florida Cardiovascular Specialists, Orlando, Fla., will present the data from the OASIS follow-up study in a Tuesday, September 22 poster session (No. 578, Hall D), from 8 a.m. to 10 a.m. PT, at the 21st annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco, sponsored by the Cardiovascular Research Foundation.

In patients with peripheral arterial disease (PAD), plaque that accumulates in leg or foot arteries reduces blood flow and leads to leg pain, immobility and potentially amputation. In the United States alone, as many as 12 million patients suffer from PAD. Cardiovascular Systems, Inc., (CSI) (Nasdaq: CSII) provides comprehensive solutions for treating PAD, including the Diamondback 360°.

“At CSI, we are committed to clinical studies that provide scientifically sound long-term data to help physicians evaluate therapies and better treat PAD patients,” said David L. Martin, president and chief executive officer. “The two-year follow-up of patients from our landmark OASIS clinical trial reinforces our excitement about treatment with the Diamondback 360°, its ability to help save legs and lives, and restore quality of life for patients and their families. Further, in this cost-conscious healthcare environment, we are mindful of the economic benefits of keeping PAD patients mobile and independent. Additional clinical studies of the Diamondback 360° are under way to further enhance our understanding of our product.”

“Our goal is to treat PAD patients, restore their ability to walk pain-free and keep their legs for life,” said Dr. Weinstock. “This two-year data of OASIS patients adds to our confidence in the safety and efficacy of the Diamondback 360°, and further encourages me to use the device as a first option in treating this prevalent disease.”

The OASIS study (Orbital Atherectomy System for the Treatment of Peripheral Vascular Stenosis), a non-randomized, IDE study, demonstrated the safety and efficacy of the Diamondback 360° in treating 124 patients with PAD with follow-up out to six months. The primary endpoints were met with a 59-percent reduction in stenosis in the 201 lesions treated and a 4-percent rate of device-related serious adverse events. No patients had major amputations, and ankle-brachial index (ABI) scores remained significantly improved ($p < 0.0001$) at six months.

A retrospective look at two-year outcomes of 64 available OASIS patients showed durable results by several measures:

- The target lesion and vessel revascularization rates (TLR/TVR), or reintervention in the originally treated lesion or vessel, were 13.6 percent and 15.5 percent, respectively.
- A 100-percent limb salvage rate was maintained.
- Ankle-brachial index (ABI) scores, a measure of blood flow to the ankle, remained significantly improved by an average score of 0.29 ($p < 0.001$) over the baseline. This subset of patients from 12 of the 17 enrolling medical centers had characteristics similar to those in the entire OASIS population. The mean age was 73 years, and 72 percent were men. In this group, 52 percent had diabetes, 81 percent had hypertension, 71 percent had hyperlipidemia (elevation of fats in the bloodstream), and 57 percent were current or former smokers. Eighty percent of the lesions were located below the knee, percent were calcified, and narrowings averaged 27 mm in length.

Additional TCT Sessions Discussing the Diamondback 360°

Several other sessions at TCT will discuss orbital atherectomy with the Diamondback 360°:

- Oral Abstract (TCT No. 59): Tuesday, Sept. 22, 10:30 a.m. PT presentation, Moscone Convention Center, Room 120
Orbital Atherectomy in the Treatment of Peripheral Arterial Occlusive Disease Below the Knee: A Large Single-Center Experience, Dr. Ragu Patlola, Regional Medical Center of Acadiana, Lafayette, La.
- Session I. Coronary Atherectomy: Wednesday, Sept. 23, 3:02 p.m., Room 133
Orbital Atherectomy and Calcified Coronary Lesions Case presenter: Dr. Keyur H. Parikh
- Session II. Peripheral Atherectomy: Wednesday, Sept. 23, 4:36 p.m., Room 133
Orbital Atherectomy in Heavily Calcified Lesions: Improved Treatment of Complex Lesion Morphologies? Case presenter: Dr. Richard R. Heuser

About Peripheral Arterial Disease

PAD is a common circulatory problem in which plaque deposits build up on the walls of blood vessels, reducing

blood flow. Plaque ranges from soft to calcified; calcified deposits are the most difficult to treat with traditional interventional procedures. In many older patients, PAD deposits are hard and calcified. PAD affects 12 percent to 20 percent of the U.S. population over age 65. With risk factors such as diabetes and obesity on the rise, the prevalence of PAD is likely to increase.

About the Cardiovascular Research Foundation

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1990, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new technologies and therapies in the subspecialty of interventional cardiology and endovascular medicine. For more information, please visit www.crf.org.

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® PAD System removes calcified and fibrotic plaque in small and large 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, almost 600 hospitals across the United States have adopted the system. For more information visit the company's Web site at www.csi360.com.