



## News Release

### Cardiovascular Systems Announces Coronary Data at Late-Breaker SCAI 2014 Scientific Sessions

- **One-year Data from Trial Shows Strong Rates of Freedom from Target Revascularization, Cardiac Death and Major Adverse Cardiac Events (MACE)**
- **New Economic Analysis Demonstrates Treatment with CSI's Coronary Orbital Atherectomy System Provides Measurable Cost Savings**

ST. PAUL, Minn.--(BUSINESS WIRE)--Jun. 4, 2014-- Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), presented one-year data and a new economic analysis from its ORBIT II coronary study in a late-breaker session at the Society for Cardiovascular Angiography and Interventions (SCAI) 2014 conference, which took place in Las Vegas, May 28-31. The ORBIT II study of the company's Diamondback 360® Coronary Orbital Atherectomy System (OAS) evaluated the safety and effectiveness of CSI's technology in treating severely calcified lesions in coronary arteries.

Dr. Jeffrey Chambers of the Metropolitan Heart and Vascular Institute, Minneapolis, presented one-year data that demonstrates freedom from target lesion revascularization and target vessel revascularization of 95 percent and 98 percent, respectively. The ORBIT II study also reported freedom from cardiac death of 97 percent.

Additionally, a key economic analysis by economist Dr. Louis Garrison, Jr., University of Washington, Seattle, was presented. Data showed that patients treated with the Diamondback 360 Coronary OAS in the ORBIT II study have been associated with shorter hospital stays and lower retreatment rates, compared to Medicare patients treated with traditional technologies, resulting in an average lower cost of \$3,200 per patient.

The Medicare comparison sample was drawn from the 100 percent Standard Analytical File for the period September 2011 through December 2012. This data, presented for the first time at SCAI 2014, builds on a previous ORBIT II economic analysis by including a larger investigation of ORBIT II subjects and both outpatient and inpatient data, versus in-patient analysis only.

"This ORBIT II data demonstrates that the orbital atherectomy system from CSI provides one-year durable results, while giving physicians a cost effective way to address coronary calcium in these difficult-to-treat patients," said Dr. Chambers.

David L. Martin, CSI president and chief executive officer, said: "ORBIT II results clearly show that by reducing severely calcified plaque with our technology, physicians not only reduce MACE and cardiac death rates, they also improve freedom from target vessel revascularization in this difficult-to-treat patient population, which lowers costs. This is important information for physicians, so we're pleased that SCAI selected our data for a late breaking presentation."

CSI completed ORBIT II enrollment of 443 patients at 49 U.S. medical centers in November 2012. On October 21, 2013, the company received PMA approval from the U.S. Food and Drug Administration (FDA) to market its Diamondback 360 Coronary Orbital Atherectomy System as a treatment for severely calcified coronary arteries.

#### **About Coronary Artery Disease (CAD)**

CAD is a life-threatening condition and leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD

increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. According to the American Heart Association, 16.3 million people in the United States have been diagnosed with CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives in the United States each year. According to estimates, significant arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention (PCI). Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (MACE).

#### **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 and heart 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, over 146,000 of CSI's devices have been sold to leading institutions across the United States. In October 2013, the company received FDA approval for the use of the Diamondback Orbital Atherectomy System in coronary arteries. For more information, visit the company's website at [www.csi360.com](http://www.csi360.com) (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.csi360.com&esheet=50879673&newsitemid=20140604005954&lan=en-US&anchor=www.csi360.com&index=1&md5=925d6f3968e57231e82e268cb37089f6>).

#### **Coronary Product Disclosure**

**Indications:** The Diamondback 360<sup>®</sup> Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions.

**Contraindications:** The OAS is contraindicated when the ViperWire<sup>®</sup> guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

**Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25 percent has not been evaluated.

See the instructions for use before performing Diamondback 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at [www.csi360.com](http://www.csi360.com) (<http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.csi360.com&esheet=50879673&newsitemid=20140604005954&lan=en-US&anchor=www.csi360.com&index=2&md5=ba77f331cf63fed14b0023e65f0a6996>).

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Source: Cardiovascular Systems, Inc.

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