Peripheral Arterial Disease Treatment Data Presented

(BUSINESS WIRE)--Cardiovascular Systems, Inc. (CSI) (Nasdaq: CSII), today announced results from a study of patients treated for peripheral arterial disease (PAD) with CSI's Diamondback(TM) Orbital Atherectomy System in a non-hospital setting. Dr. Warren Swee, South Florida Vascular Associates, Coconut Creek, Fla. discussed his analysis of data demonstrating device safety and efficacy treating calcified lesions in the office-based lab (OBL) setting at the Society for Interventional Radiology (SIR) Annual Scientific Meeting in San Francisco.

In this prospective, single-center study, 100 consecutive procedures were performed on 84 patients (157 vessels) over a nine-month period by Dr. William Julien, chief executive officer of South Florida Vascular Associates. Of these patients, 64.9 percent had claudication and 35.1 percent had critical limb ischemia. The mean atherectomy run time was only 55 seconds. Low-pressure adjunctive angioplasty was performed in all cases. The average pre-procedure vessel stenosis was 78 percent; after treatment, mean vessel stenosis was 11 percent. The dissection rate was only 2.8 percent, none of which were flow limiting, and no perforations were reported. All patients were discharged to their homes, with no hospital transfers. There were no cases of hospital admission or major adverse events within 24 hours.

"With today's growing economic pressures, office-based endovascular suites are becoming more common as physicians look for opportunities to assert more control over the patient care process and enhance practice productivity," said Dr. Swee. "These data show that CSI's Diamondback Orbital Atherectomy System can be safely used for treating calcified lesions in the OBL setting, with the positive patient outcomes consistent with those seen in the hospital environment."

David L. Martin, CSI president and chief executive officer, added: "This study demonstrates that patients with moderate to severe calcium can receive excellent clinical outcomes in hospital and non-hospital settings. We are excited to show that patients, physicians and payors can benefit from CSI's clinically proven product - in both settings."

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