CARDIOVASCULAR SYSTEMS PRESENTS REACH PVI STUDY AT THE NEW CARDIOVASCULAR HORIZONS CONFERENCE

St. Paul, Minn., July 27, 2020 – Cardiovascular Systems, Inc. (CSI®) (NASDAQ: CSII), a medical device company developing and commercializing innovative interventional treatment systems for patients with peripheral and coronary artery disease, today announced that the results from its REACH PVI study were presented at the New Cardiovascular Horizons (NCVH) Conference. This study prospectively evaluated acute clinical outcomes of orbital atherectomy via transradial access for the treatment of peripheral artery disease (PAD) in lower extremity lesions.

CSI’s low profile 5Fr, Extended Length Diamondback 360® and Stealth 360® Peripheral Orbital Atherectomy Systems (OAS) are the only atherectomy systems that allow radial access for the treatment of peripheral lesions.

The results of the REACH PVI study demonstrated that the use of orbital atherectomy in radial peripheral vascular interventions has a high rate of procedural and treatment success and is effective in reducing residual stenosis across all lesions. Ninety-eight percent of patients achieved procedural and treatment success. There were no reports of serious transradial access related events. Additionally, the study demonstrated short recovery time and length of stay, key factors in patient satisfaction.

National Primary Investigator for REACH PVI, Dr. Ankur Lodha, MD, Interventional Cardiologist, Cardiovascular Institute of the South, Lafayette, La., said, “It’s a fascinating time for peripheral interventions because the entire case can be done solely with radial artery access. Radial access can lead to better patient satisfaction and comfort, improved patient safety and is also beneficial to healthcare economics. CSI is leading the way with their peripheral orbital atherectomy device as it’s the only atherectomy system available that is designed to treat through the radial artery.”

Scott Ward, CSI Chairman, President, and Chief Executive Officer, said, “The positive data from REACH PVI confirms our belief that our low-profile OAS is uniquely positioned to safely treat patients suffering from PAD. Using an alternative access site, like radial, can provide shorter recovery time for patients, and reduced length of stay compared to femoral access. Our investment in this technology, and studies like REACH PVI, demonstrate our ongoing commitment to advancing medical evidence to support physicians and the patients they serve.”

About REACH PVI
REACH PVI (RADIAL ACCESS FOR NAVIGATION TO YOUR CHOSEN LESION FOR PERIPHERAL VASCULAR INTERVENTION) is a prospective, observational, single-arm, multi-center post-market study that enrolled 50 patients at 6 sites across the United States. The purpose of this study was to prospectively evaluate acute clinical outcomes of orbital atherectomy via transradial access for treatment of peripheral artery disease (PAD) in lower extremity lesions. The study included CSI orbital atherectomy devices FDA-cleared for treatment of PAD. More information about the study design is available at www.ClinicalTrials.gov; identifier: NCT03943160.

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 system treats calcified and fibrotic plaque in arterial vessels throughout the leg and heart and addresses many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. For additional information, please visit www.csi360.com and connect on Twitter @csi360.
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 provided under the protection of the safe harbor for forward-looking statements provided by that Act. These statements involve risks and uncertainties that could cause results to differ materially from those projected, including, but not limited to, the factors detailed from time to time in CSI’s SEC reports, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. 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.

Product Disclosure:

Peripheral Products

Indications: The Stealth 360® PAD System and Diamondback 360® PAD System are percutaneous orbital atherectomy systems (OAS) indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae.

Contraindications: The OAS are contraindicated for use in coronary arteries, bypass grafts, stents or where thrombus or dissections are present.

Warnings/Precautions: 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. See the instructions for use 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.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. The Stealth 360® PAD System and Diamondback 360® PAD System received FDA 510(k) clearance. The Stealth 360® PAD System is CE Marked.

Contact:
Cardiovascular Systems, Inc.
Jack Nielsen
(651) 202-4919
j.nielsen@csi360.com

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