



## **CARDIOVASCULAR SYSTEMS, INC. ANNOUNCES FIRST COMMERCIAL LAUNCH OF PERIPHERAL ORBITAL ATHERECTOMY SYSTEM OUTSIDE THE UNITED STATES**

### ***Patient Treated in Hong Kong Marks Company's First Product Launch Leveraging International Distribution Partnership with OrbusNeich***

**St. Paul, Minn., September 19, 2018** – 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, announced today that the first patient in Hong Kong has been treated with its Stealth 360® Peripheral Orbital Atherectomy System (OAS). The Hong Kong case is the first commercial use of Peripheral OAS outside of the United States.

Dr. Bryan Yan, Associate Professor, Chinese University of Hong Kong, who treated the first patient in Hong Kong, said, "Patients with severely calcified peripheral arteries can be difficult to treat due to the limitations of traditional angioplasty or stenting. This can also place patients at risk for subsequent complications including repeat interventions and amputation. The commercialization of the Stealth 360® OAS in Hong Kong provides physicians with a minimally invasive treatment option for this complex patient population. I am very satisfied with the procedural outcome for my patient because I was able to avoid implanting a stent in the distal superficial femoral artery and I look forward to continuing treatment of similar patients with this technology."

Said Scott Ward, Chairman, President and Chief Executive Officer of CSI. "We are pleased that the first patient treated with OAS in conjunction with our international distribution partner, OrbusNeich, was a success. This positive outcome demonstrates our mutual mission to support physicians in treating patients with peripheral artery disease."

Scott Addonizio, Senior Vice President and Chief Operating Officer of OrbusNeich, concluded, "Our experienced sales force is thrilled to bring CSI's orbital atherectomy technology to Hong Kong. This first procedure occurred only two months after becoming CSI's international distribution partner. We look forward to introducing CSI's atherectomy technology to physicians in new markets in the months and years ahead."

In July 2018, CSI announced that it had signed an exclusive international distribution agreement with OrbusNeich to sell its coronary and peripheral OAS outside of the United States and Japan.

In January 2018, CSI announced that it was the exclusive U.S. distributor for OrbusNeich® balloon products. Ultimately, CSI will offer a full line of semi-compliant, non-compliant and specialty balloons for both coronary and peripheral vascular procedures. OrbusNeich® PCI balloons include the Sapphire® II Pro, the first and only 1.0mm coronary balloon available in the United States.

In November 2016, CSI announced that Medikit, Co., Ltd. signed an exclusive distribution agreement to sell its coronary and peripheral OAS in Japan.

#### **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 peripheral arteries in August

2007. In October 2013, the company received FDA approval for the use of the Diamondback Orbital Atherectomy System in coronary arteries. The Stealth 360® Peripheral Orbital Atherectomy System (OAS) received CE Mark in October 2014. As of June 30, 2018, over 392,000 of CSI's devices have been sold to leading institutions across the United States and Japan.

### **About OrbusNeich**

OrbusNeich is a global pioneer in the provision of life-changing vascular solutions and offers an extensive portfolio of products that set industry benchmarks in vascular intervention. Current products include the world's first dual therapy stents, the COMBO Plus and COMBO Dual Therapy Stents, together with stents and balloons marketed under the names of Azule®, Scoreflex®, Sapphire® II, Sapphire® II PRO and Sapphire® II NC, as well as products to treat peripheral artery disease: the Jade® and Scoreflex® PTA balloons. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Florida, USA; Hoevelaken, The Netherlands; and Tokyo, Japan. OrbusNeich supplies medical devices to physicians in more than 60 countries. For more information, visit [www.OrbusNeich.com](http://www.OrbusNeich.com).

### **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. For example, statements in this press release regarding anticipated future introduction of CSI devices outside of the United States and Japan; the specific OrbusNeich products to be offered by CSI in the United States; and the sale of CSI products in Japan, are forward-looking statements. These statements involve risks and uncertainties that could cause results to differ materially from those projected, including, but not limited to, regulatory developments, clearances and approvals; approval of our products for distribution in countries outside of the United States; approval of our products for reimbursement in and the level of reimbursement; the ability of OrbusNeich to successfully launch CSI products outside of the United States and Japan; the experience of physicians regarding the effectiveness and reliability of CSI's products; the reluctance of physicians, hospitals and other organizations to accept new products; the impact of competitive products and pricing; general economic conditions; international trade developments; and other 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**

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.

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

### **Contacts:**

#### **Cardiovascular Systems, Inc.**

Jack Nielsen  
(651) 202-4919  
[j.nielsen@csi360.com](mailto:j.nielsen@csi360.com)

#### **Padilla:**

Matt Sullivan  
(612) 455-1709  
[matt.sullivan@padillaco.com](mailto:matt.sullivan@padillaco.com)

# # #