Robotic Angioplasty Achieves 97.6 Percent Clinical Success Rate

Business Wire

Publication of PRECISE Trial Results in The Journal of American College of Cardiology builds on momentum of FDA clearance and commercialization of the CorPath® System.

Corindus Vascular Robotics, a leading developer of precision vascular robotics [1], today announced that the Journal of American College of Cardiology published the results from its CorPath® PRECISE (Percutaneous Robotic-Enhanced Coronary Intervention) study in the April 2013 issue (Vol. 61, No. 15, 2013). Results of the trial demonstrate the CorPath System is safe and feasible for patients, with significantly lower harmful radiation exposure to the operator.

“Building on the momentum of the FDA clearance of the CorPath System in July 2012, the publication of the PRECISE trial results in the leading medical journal for cardiology only further validates the positive feedback we are receiving from clinicians who are using the CorPath System in their day-to-day practice,” said David M. Handler, president and CEO of Corindus. “Patients with coronary artery disease now have access to robotic angioplasties at leading medical centers across the U.S. including NewYork-Presbyterian Hospital/Columbia University Medical Center, St. Elizabeth’s Medical Center, Detroit Medical Center, Sanford Health and Northeast Georgia Health System.”

The study, led by the Co-Principal Investigators Giora Weisz, M.D., director, clinical cardiovascular research, NewYork-Presbyterian Hospital/Columbia University Medical Center, and Joseph P. Carrozza, M.D., Chief of Cardiovascular Medicine at St. Elizabeth’s Medical Center in Boston, was a prospective, single-arm, multicenter, open-label, non-randomized study, enrolling 164 patients at nine clinical trial sites.

“The PRECISE trial is the first large-scale, multicenter study evaluating the safety and efficacy of robotic-assisted angioplasties [2],” said Dr. Weisz. “We are excited about the results of the study, which demonstrates that robotic angioplasty is safe for patients and is a practical tool for our day-to-day practice.”

The primary endpoint of clinical procedural success was achieved in 97.6 percent of patients, and device technical success was achieved in 98.8 percent. Additionally, a secondary endpoint of the trial was the reduction in radiation exposure to the physician. Researchers determined the CorPath System significantly lowered radiation exposure by 95.2 percent compared to levels found when a physician performs the procedure at the patient’s bedside. Although operator comfort was not measured in the study, researchers noted the ability to perform procedures in a seated position without a heavy lead apron provides relief for back discomfort and allows the operator to focus solely on the patient.

“The clinical validation of the PRECISE trial demonstrates that robotic-assisted angioplasties are now a reality,” said Dr. Carrozza. “Currently being used in my daily practice, I have witnessed first-hand the effectiveness of the technology to improve back strain and visualization when I perform the procedure, as well as its ability to provide millimeter-by-millimeter control when placing stents.”

Traditionally, angioplasty procedures are performed manually, where an interventional cardiologist inserts a guidewire with a stent or balloon attached to physically open an artery blockage and help improve blood flow. While angioplasty procedures remain one of the most frequently performed procedures in the United States with nearly one million cases annually, the procedure has remained largely unchanged for decades. A CorPath robotic angioplasty [3] allows interventional cardiologists to perform the procedure remotely, away from the patient bed side. Seated in a radiation-protected cockpit, the physician uses a joystick to robotically advance catheters, angioplasty balloons and stents to clear the blockage and restore blood flow. Additionally, the technology provides interventional cardiologists with the ability to accurately measure anatomy and precisely control stents.

“At Sanford Health, we implemented two CorPath Systems in December, and we have already performed 34 procedures. Using a joystick, I am able to advance the catheter millimeter-by-millimeter through the artery and achieve enhanced control when placing the stent,” said Tom Stys, M.D., FACC, FSCAI, Medical Director Sanford Heart Hospital and Cardiovascular Services, Sioux Falls, South Dakota. “With an increasing amount of complex procedures being performed, we feel it is essential to invest in new technology that will help physicians provide enhanced patient care.”

“As the adoption of the CorPath System continues to grow, Corindus will maintain its strong commitment to clinical research,” added Handler. “We are investing in clinical research programs to quantify the patient benefits of the CorPath System as well as investigate potential future indications such as peripheral, neurology and structural heart.”

Corindus Vascular Robotics will be providing hands-on demonstrations of the CorPath System [4]at the Society for Cardiovascular Angiography and Interventions’ (SCAI [5]) Scientific Sessions, May 8-11, 2013 at The Peabody Orlando. To learn more about the System or reserve a demonstration at booth 1203, please call 508.653.3335 x200 or emailSCAI2013@corindus.com [6].

About the CorPath PRECISE Trial
The CorPath PRECISE Study was sponsored by Corindus Vascular Robotics under the Investigational Device Exemption (IDE) approval from the FDA to obtain 510(k) clearance. The study was a prospective, single-arm, multicenter, open-label, non-randomized study, enrolling 164 patients at nine clinical trial sites. Physicians participating in the study did not receive any direct financial compensation.

About Corindus Vascular Robotics
Corindus Vascular Robotics (http://www.corindus.com [7]) is the global technology leader in robotic-assisted percutaneous coronary interventions (PCI). The

Company's FDA cleared CorPath® 200 System is the first medical device that offers interventional cardiologists PCI procedure control from an interventional cockpit. The CorPath open-platform technology and intellectual property will enable Corindus to address other segments of the vascular market, including peripheral, neuro and structural heart applications.

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