



Media Contacts:

Corindus Vascular Robotics
Darcy Sheerin
(508) 653-3335 ext. 202
Darcy.Sheerin@corindus.com

Schwartz Communications
Krystin Hayward/ Matthew Weaver
(781) 684-0770
corindus@schwartzcomm.com

Corindus Vascular Robotics Announces FDA Conditional Approval for Pivotal Study to Evaluate Robotic-Assisted Placement of Coronary Guidewires and Stent/Balloon Catheters

NATICK, Mass. –January 26, 2011 – Corindus Vascular Robotics, a leading developer of precision [vascular robotics](#), today announced it has been granted Food and Drug Administration (FDA) conditional Investigational Device Exemption (IDE) approval to evaluate the safety and effectiveness of its CorPath® 200 System in delivering and manipulating coronary guidewires and stent/balloon systems in [percutaneous coronary interventions](#) (PCI) procedures. With this approval, Corindus is authorized to begin its pivotal trial, CorPath PRECISE. The trial is a prospective, single-arm, multi-center, study, which will initially enroll 154 patients.

“Interventional cardiologists perform hundreds of PCI procedures each year,” said Giora Weisz M.D., co-principal investigator, Assistant Professor, Columbia University College of Physicians and Surgeons, New York. “By utilizing the CorPath System, we hope to demonstrate both precision and accuracy of robotically-assisted PCI procedures.”

PCI is performed by an interventional cardiologist in a catheterization laboratory (cath lab) utilizing X-ray angiography imaging. Interventional cardiologist’s daily exposure to radiation and the physical stresses inherent in the cath lab can lead to occupational health risks— including orthopedic problems, cataracts and cancer, according to recent data published in [Catheterization and Cardiovascular Intervention journal](#). The CorPath 200 System allows for controlled robotic-assisted placement of coronary guidewires and stent/balloon catheters from an ergonomically optimized interventional cockpit. The lead-lined cockpit protects the operator from radiation exposure. The comfortable seated position in front of the “slaved” monitors provides enhanced visualization of the angiography screen while reducing fatigue and minimizes head, neck and back strain.

While the clinical endpoint of the trial is the ability to treat the patient without the incidence of major adverse cardiovascular events (MACE), the trial will be closely monitoring the radiation exposure of interventional cardiologist while using the CorPath technology compared to the radiation exposure if the operator was performing the procedure at the table.

“Improving precision of PCI procedures and the ergonomic conditions of the cath lab will ultimately improve patient procedures,” said Joseph P. Carrozza, Jr. M.D., co-principal investigator and Chief of Cardiovascular Medicine at St. Elizabeth’s Medical Center in Boston. “The CorPath System allows interventional cardiologists to operate in a comfortable environment, completely focused on the patient’s physiology. The ergonomically optimized cockpit enhances visualization, while minimizing fatigue, radiation exposure and other occupational hazards, such as back strain.”

The CorPath PRECISE (Percutaneous Robotic-Enhanced Coronary Intervention Study) trial will be conducted at leading medical centers across the United States, including Columbia University Medical Center in New York, St. Elizabeth's Medical Center in Boston, Virginia Commonwealth University Medical Center in Richmond, Va. and, St. Joseph's Hospital Health Center in Syracuse, New York. The results of this study will be the basis for a Pre-market clearance (510(k)) application to the FDA.

"The initiation of the CorPath PRECISE trial is a tremendous milestone for Corindus," said David M. Handler, President and CEO of Corindus "We believe the CorPath System has the potential to raise the standard of care in PCI by cost effectively improving procedure results, while ultimately extending the physician's capability and career."

The first procedures in the trial are targeted for early 2011. Previously, Corindus Vascular Robotics completed its first-in-human [clinical trial](#) with CorPath 200 System in March 2010. These results met the company's safety and efficacy endpoints and were among the data the FDA considered in granting conditional IDE approval.

About Corindus

Corindus (<http://www.corindus.com>) is the global technology leader in robotic-assisted percutaneous coronary interventions. The company's CorPath® 200 System is the first medical device that offers interventional cardiologists complete 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

NOTE: The CorPath 200 System is an investigational device and limited by federal law to investigational use only.