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Corindus announces results of First-in-Human clinical study of CorPath[®] 200 System; TCT 2010 attendees invited to experience the system firsthand

Natick, MA. (September 20, 2010) – Corindus Vascular Robotics (www.corindus.com) announced the results of the first clinical study of the CorPath[®] 200 System and invites attendees of the Transcatheter Cardiovascular Therapeutics (TCT) 2010 conference (September 21-25 in Washington, DC) to experience firsthand the CorPath 200 System.

First-in-Human Clinical Study

The first-in-human clinical study of the CorPath 200 System performed at the Corbic Research Institute, Envigado, Colombia, was conducted on eight patients to evaluate the safety and technical efficacy of the system in delivering and manipulating coronary guidewires and stent/balloon systems in PCI procedures. The principal investigator was Juan F. Granada, M.D., medical director, Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation (CRF). Juan Andreas Delgado, M.D., director of the Catheterization Laboratory at Corbic Research Institute, also participated in the study, as did Giora Weisz, M.D., Assistant Professor, Columbia University and Director of Research, Center for Interventional Vascular Therapy, New York-Presbyterian Hospital/Columbia University Medical Center.

“The trial reached its primary endpoint of zero MACE at 48 hours,” Dr. Granada says. “I was impressed by the CorPath 200 System’s ability to precisely control and deliver the guidewire and other angioplasty devices to the target lesion. It definitely helped to perform the procedure in a highly controlled manner. Conducting the procedure while sitting in the system’s cockpit gave me more control and better focus on my patient than I would have achieved standing alongside the procedure table.”

“The procedure time, including setup and patient turnover, was similar to conventional manual operation, which is impressive considering this was the first time we used the CorPath 200 System at my center,” Dr. Delgado says. All eight patients in the study were discharged with less than 30 percent stenosis following their procedures, and a 30-day follow-up was completed without occurrence of MACE.

Corindus CEO David Handler says the ergonomic design of the CorPath 200 System gives physicians a better environment that improves the physician’s ability to focus, enhances visualization, and offers precise robotic-assisted control.

“The first-in-human clinical study of the CorPath 200 System shows that for the first time a physician can execute an entire PCI procedure precisely and accurately without the pain, distraction and fatigue of manual procedures.” Handler says.

According to Dr. Weisz, the CorPath 200 System represents a paradigm shift in the control of PCI procedures and a major step toward a healthier and safer environment for physicians who spend increasingly longer hours in cath labs.

“The CorPath 200 System allows me to perform a PCI procedure while sitting comfortably in the interventional cockpit without the strain of a heavy lead apron,” says Dr. Weisz, adding that his exposure to radiation dropped drastically. “During the study, my mean radiation exposure without a lead apron was only 1.81 μ Gy. That is 97% less than I would have received had I worn an apron and performed the same procedures manually. The system was also very intuitive and easy to use.”

Based on the success of the first clinical trial, Corindus looks forward to its Percutaneous Robotically Enhanced Coronary Intervention Study, Handler says. The “CorPath PRECISE” trial is a prospective, single-arm, multi-center, non-randomized study.

“We’re extremely excited about the progress we continue to make in bringing the CorPath 200 System to market,” Handler says. “We’re even more excited about what this means for physicians and patients. We believe that a new robotic tool that improves procedure execution will ultimately help to further improve outcomes.”

Corindus related activities at TCT 2010

Visitors to the conference will have the opportunity to:

- Experience the CorPath 200 System simulated PCI at Corindus’ booth (#2049).
- Attend a presentation by Dr. Weisz at 10:40 am on Tuesday, September 21, 2010. Dr. Weisz’ presentation is entitled, “Robotic-Assisted Angioplasty: First In-Human Experiences with the Corindus System.”
- Review a poster presentation by Dr. Juan Granada et al, entitled, “Robotically-Assisted PCI: First in Human Study,” on Wednesday September 22, 2010. The presentation is #331.

To make an appointment for an individual hands-on demonstration of the CorPath 200 System at TCT 2010, call 1-508-653-3335 x213, or email Corindus at TCT2010@corindus.com.

About Corindus

Corindus (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.