Covidien Completes Patient Enrollment in Iliac Stent Clinical Study Series

The Associated Press

MANSFIELD, Mass.--(BUSINESS WIRE)--Feb 20, 2013--Covidien (NYSE: COV), a leading global provider of healthcare products, today announced the completion of patient enrollment in its iliac stent clinical study series. The series is composed of two prospective, multinational, multicenter studies - VISIBILITY Iliac and DURABILITY Iliac.

Each study is designed to evaluate the safety and effectiveness of using either balloon expandable or self-expanding stents to treat peripheral arterial disease (PAD) in the common iliac and external iliac arteries. Located in the lower abdomen, the common iliac and external iliac arteries are the main conduits delivering blood to the arteries in the legs.

According to the American Heart Association, approximately eight million people in the U.S. suffer from PAD 1, which affects blood vessels throughout the body. When the vessels become clogged with plaque, blood flow slows or stops. If left untreated in vessels either leading to or located in the legs or feet, this condition can lead to severe pain when walking, gangrene and even amputation.

“We are very pleased to report the completion of enrollment in these two studies, as the results will add important clinical data around treatment for patients with PAD,” said Mark A. Turco, MD, Chief Medical Officer, Vascular Therapies, Covidien. “The results of the studies will enable physicians to make evidence-based decisions to allow for optimal patient outcomes. Covidien remains committed to bringing clinical data to the forefront, while working toward obtaining important disease and anatomic- specific labeling indications for our products.” VISIBILITY Iliac and DURABILITY Iliac Study Designs VISIBILITY Iliac and DURABILITY Iliac are prospective studies being conducted at 23 centers in the U.S. and Europe. Of the 150 patients enrolled in the studies, 75 were treated with the Visi-Pro™ balloon expandable stent system in VISIBILITY Iliac, and 75 were treated with either the EverFlex™ self-expanding stent system or the Protégé™ GPS™ self-expanding nitinol stent and delivery technology in DURABILITY Iliac. Primary effectiveness of the stents and incidence of major adverse events will be evaluated through nine months, and patients in the study will be followed for a total of three years.

“The completion of enrollment in the VISIBILITY Iliac Study marks a significant milestone in the progress toward completion of this important Phase II trial,” said Peter L. Faries, MD, Chief of Vascular Surgery at Mount Sinai School of Medicine in New York. “Enrollment was completed well ahead of schedule. We believe the rapid enrollment reflects both enthusiasm for the promise of this technology and the unique trial design that allowed treatment of concurrent infrainguinal occlusive disease if needed by the patient.” “Aortoiliac occlusive disease remains an

important cause of vascular disability," added John H. Rundback, MD, Medical Director of the Interventional Institute at Holy Name Medical Center in Teaneck, New Jersey. "We believe the outcomes from the DURABILITY Iliac study will validate the effectiveness of the self-expanding EverFlex and GPS stents, supporting the role of endovascular treatment in patients with both simple and complex iliac lesions to improve and maintain quality of life. The combined DURABILITY Iliac and VISIBILITY Iliac studies will provide a comprehensive evaluation of two complementary stent systems for the successful resolution of symptomatic aortoiliac obstructions." Dr. Faries and Dr. Rundback served as Co-Principal Investigators for both the DURABILITY Iliac and VISIBILITY Iliac studies.

About the Covidien EverFlex and GPS Self-Expanding Stents
Part of Covidien's extensive stent portfolio, the EverFlex self-expanding stent system and the Protégé GPS self-expanding nitinol stent and delivery technology offer a distinctive design that provides a unique combination of flexibility, strength and precision needed to maintain vessel patency while minimizing fractures. These stents offer a robust size matrix, enabling physicians to treat a broad range of patient anatomies.

About the Covidien Visi-Pro Balloon Expandable Stent
The Visi-Pro balloon expandable stent is Covidien's best-selling balloon expandable stent system. In the U.S., Visi-Pro is the only 0.035" balloon expandable stent that offers radiopaque tantalum GPS markers on the distal and proximal ends of the stent, enhancing visualization both during and after stent placement.

About Covidien
Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2012 revenue of $11.9 billion, Covidien has 43,000 employees worldwide in 70 countries, and its products are sold in over 140 countries. Please visit www.covidien.com to learn more about our business.

1. Hirsch AT, Criqui MH, Treat-Jacobson D, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA:The Journal of the American Medical Association. Sep 19 2001;286(11):1317-1324.

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http://www.mdtmag.com/news/2013/02/covidien-completes-patient-enrollment-iliac-stent-clinical-study-series