Covidien Announces Five-Year Results from the ClosureFast™ Long-Term European Multi-Center Study in Patients with Lower Limb Venous Disease

The Associated Press

MANSFIELD, Mass.--(BUSINESS WIRE)--Dec 20, 2012--Covidien (NYSE:COV), a leading global provider of healthcare products, today announced the five-year results of the ClosureFast™ Long-Term European Multi-Center Study in patients with Chronic Venous Insufficiency (CVI). This study evaluates the five-year outcomes of a minimally invasive endovascular therapy for treatment of CVI.

Covidien's ClosureFast catheter was successfully used in the European Multi-Center Study in patients with lower limb venous disease (Photo: Business Wire) The ClosureFast Study was conducted prospectively at eight centers in Europe. The Venefit™ procedure (using the ClosureFast radiofrequency ablation catheter) was used to treat 295 lower limbs in 225 patients diagnosed with superficial venous reflux, the underlying cause of varicose veins and CVI. This progressive medical condition affects the veins in the leg and compromises their ability to carry blood back to the heart. This is a worldwide issue and, in fact, impacts over 30 million Americans in the United States alone. 1 If left untreated, varicose veins can advance to CVI, which, in severe cases, may result in lower leg pain, skin damage, and leg ulcerations.

"The five-year final analysis from the ClosureFast Study shows sustained treatment success in anatomical and clinical categories and supports its leading position in endovenous vein treatment," said Thomas Proebstle, MD, Universitaets Hautklinik Heidelberg, Germany, who recently delivered the study results at the American College of Phlebology 26 th Annual Congress.

ClosureFast Study Design and Five-Year Results This prospective, multi-center study enrolled 225 patients and treated 295 limbs at eight centers in Europe from April 2006 to June 2007. The study treated patients diagnosed with superficial venous reflux with the minimally invasive Venefit procedure using the ClosureFast radiofrequency ablation catheter.

Patients were evaluated following the procedure by duplex ultrasound imaging and clinical examination at three days, three months, six months and in yearly intervals up to five years. Of the 295 treated limbs, 233 (79%) were available for examination at five years. According to Kaplan-Meier analysis, at five-year follow-up, full occlusion of the treated vein was observed in 92% of patients (vs. 98% at one year). The vast majority (95%) of patients were free of pathological venous reflux (vs. 99% at one year). This demonstrates durable results of the Venefit™ procedure out to five years.

The average Venous Clinical Severity Score (a multifactorial score measuring disease severity and quality of life) improved from 3.9 ± 2.1 before treatment to 1.3 ± 1.7 at 5 years. In addition, only 14% of limbs were CEAP (disease severity classification) class 3 or higher at 5 years, while, at baseline, 48% of limbs were in the same category.

“This pivotal study provides substantial long-term data on relevant end-points to help clinicians decide the appropriate treatment for their patients, thus defining Covidien’s commitment to a strong foundation of clinical research,” said Mark A. Turco, MD, Chief Medical Officer, Vascular Therapies, Covidien.

About CVI and the Venefit Procedure CVI, or Chronic Venous Insufficiency, is a progressive, sometimes debilitating medical condition. It occurs when valves in the veins of the lower leg no longer function to push blood back to the heart. This allows blood to flow backward, or reflux resulting in enlarged, or varicose, veins. If left untreated, the condition can progress, and, in severe cases, can result in lifestyle-limiting lower leg pain, skin damage and ulcerations. Traditional surgical treatments that close or remove the diseased veins, including vein stripping, may be painful and can result in long recovery times for patients. ii Alternatively, patients can be treated with a minimally invasive endovascular procedure such as the Venefit procedure. During the Venefit procedure, the ClosureFast catheter is inserted into the diseased vein and radiofrequency energy is used to seal the vein shut. Blood that would normally return to the heart through the diseased vein travels back through other veins instead. Over time, the treated vein shrinks and is absorbed by the body. Compared with surgical options, minimally invasive ablation of the vein can result in less pain and quicker recovery time. ii 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 Gloviczki P, et al. The care of patients with varicose veins and associated chronic diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. JVS; May 2011. ii L. H. Rasmussen, M. Lawaetz, L. Bjoern, B. Vennits, A. Blemings, and B. Eklof, Randomized Clinical Trial Comparing Endovenous Laser Ablation, Radiofrequency Ablation, Foam Sclerotherapy and Surgical Stripping for Great Saphenous Varicose Veins. British Journal of Surgery Society Ltd, Wiley Online Library, www.bjs.co.uk, March 15, 2011.

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CONTACT: Vascular Therapies David T. Young, 508-452-1644 Manager, External Communications david.young@covidien.com or Bruce Farmer, 508-452-4372 Vice President Public Relations bruce.farmer@covidien.com or Coleman Lannum, CFA,

508-452-4343 Vice President Investor Relations cole.lannum@covidien.com or Todd Carpenter, 508-452-4363 Director Investor Relations todd.carpenter@covidien.com
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