# Covidien Announces Publication of Final Results of Pipeline Embolization Device Pivotal Study

Business Wire

Covidien (NYSE:COV), a leading global provider of healthcare products, today announced that the final results of the PUFs (Pipeline for Uncoilable or Failed Aneurysms) clinical study of its Pipeline™ embolization device have been published in the June issue of Radiology.[1] Radiology is the official peer-reviewed medical journal of the Radiological Society of North America.

The Pipeline device met the trial's primary endpoints for both effectiveness and safety. Based on these data, the Pipeline device was approved by the U.S. Food and Drug Administration (FDA) on April 6, 2011.

"Patients with an unruptured large or giant wide-necked aneurysm in the internal carotid artery are at significant risk of death or a highly disabling stroke and other significant neurologic complications if the aneurysm bursts or pushes on surrounding nervous tissues," said principal investigator Tibor Becske, MD, assistant professor, Departments of Radiology, Division of Neuro Interventional Radiology and Neurology at NYU Langone Medical Center in New York. "This study of highly complex aneurysms confirms that, for certain patients, there is a safe and effective minimally invasive procedure to address the underlying pathology of the aneurysm – allowing the vessel to heal over time." A brain aneurysm is a weak, bulging area on the wall of an artery in the brain. Over time, the blood flow and pressure within the artery gradually weaken the arterial wall, which can result in a rupture and the release of blood into the space around the brain.

"The Pipeline device offers hope for those patients who have had poor alternatives for treating this often debilitating and sometimes fatal medical condition," said Christine Buckley, Executive Director of the Brain Aneurysm Foundation. "We're pleased that Covidien dedicated itself to generating clinical evidence supporting new innovative devices that have helped many patients in our community overcome an incredibly frightening and serious diagnosis so they can go on to live normal lives." Traditional endovascular methods of treating these aneurysms have included a reconstructive approach of filling the aneurysm sac with an embolic material (usually detachable coils), or parent artery occlusion, where doctors attempt to close off the affected artery. However, neither of these approaches addresses the underlying pathology of the aneurysm.[2-5] Overall, 108 patients were enrolled into the study. Of the 106 evaluable aneurysms that were treated with one or more Pipeline devices, 73.6% completely closed (p-value <.0001) without the use of an alternative treatment. Importantly, the occlusion rate in these patients also improved over time, reaching 86.8% complete occlusion at one-year follow-up. These occlusion rates are significant, especially for this challenging patient population.

Investigators compared the Pipeline device to historical controls because no other blood flow diverting devices are available in the U.S. Effectiveness of stents has not been proven to FDA standards; and outcomes for surgical or other endovascular treatments have been suboptimal.

Investigators measured safety of the device by the number of patients who suffered an ipsilateral stroke or neurologic death in the 180 days following the procedure. In the study, six of 107 (5.6%) patients (p-value <.0001) suffered one of these events, significantly less than the predefined safety threshold of 20%. The 20% threshold was based on a literature review of adverse events rates associated with other current procedures and therapies.

“Covidien remains committed to delivering clinical data to help redefine how neurointerventionalists treat large and giant wide-necked aneurysms,” said Mark A. Turco, M.D., Chief Medical Officer, Vascular Therapies, Covidien. “The publication of the PUFs pivotal data represents an important milestone for the company and we look forward to continuing to work with the medical community to deliver additional evidence to support new treatment options for patients.” Note: Dr. Becske is a paid consultant for Covidien. 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] Becske T, Kallmes DF, Saatci I, et al. Pipeline for Uncoilable or Failed Aneurysms: Results from a Multicenter Clinical Trial. Radiology. Published online before print February 15, 2013, doi: 10.1148/radiol.13120099
[2] Campi A, Ramzi N, Molyneux AJ, et al. Retreatment of Ruptured Cerebral Aneurysms in Patients Randomized by Coiling or Clipping in the International Subarachnoid Aneurysm Trial (ISAT). Stroke 2007; 38(5): 1538-44.
[3] Molyneux A, Kerr R, Stratton I, et al. International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomized trial. J Stroke Cerebrovasc Dis 2002; 11(6): 304-14.
[4] Molyneux AJ. Indications for treatment of cerebral aneurysms from an endovascular perspective: the creation of an evidence base for interventional techniques. Neurosurgery clinics of North America 2005; 16(2): 313-6, ix.
[5] Molyneux AJ, Kerr RS, Birks J, et al. Risk of recurrent subarachnoid haemorrhage, death, or dependence and standardised mortality ratios after clipping or coiling of an intracranial aneurysm in the International Subarachnoid Aneurysm Trial (ISAT): long-term follow-up. Lancet Neurol 2009; 8(5): 427-33.

**Source URL (retrieved on *07/31/2014 - 11:06pm*):**
http://www.mdtmag.com/news/2013/06/covidien-announces-publication-final-results-

pipeline-embolization-device-pivotal-study