Endologix Announces Publication of Clinical Trial Results Supporting Anatomical Fixation with a Suprarenal Aortic Extension


The trial demonstrated 100% procedural technical success, with no aneurysm-related mortality, no conversions to open repair, no aneurysm ruptures, and no device migrations. In addition, core laboratory assessments of aneurysm and stent graft imaging results identified no stent fracture or graft failure, no Type III or Type IV endoleaks, and significantly reduced mean aneurysm sac diameter at the current two-year follow-up.

Stuart A. Harlin, MD (Sacred Heart Hospital, Pensacola, FL and trial investigator) said, "In applying evidence-based medicine to the treatment of AAA, it is clear that these results, coupled with prior multicenter trial published results, demonstrate the significant clinical benefits of the anatomical fixation technique. This is particularly important in patients with challenging aortic neck anatomy, as seen in 93% of patients in this trial. As a physician who prefers suprarenal placement to maximize proximal seal, I am delighted to have the benefits of anatomical fixation coupled with a suprarenal aortic extension."

The trial publication, which is titled "Endovascular abdominal aortic aneurysm repair using an anatomical fixation technique and concomitant suprarenal orientation: results of a prospective, multicenter trial," is currently available online in the Annals of Vascular Surgery, and will be published in the October issue of the journal. The publication was authored by site principal investigators Stuart A. Harlin, MD, Robert E. Beasley, MD, Robert L. Feldman, MD, Charles S. Thompson, MD, and James B. Williams, MD. Conducted at eight U.S. centers per FDA regulations and international clinical trials standards, the 44-patient trial was designed to assess the safety and effectiveness of the Powerlink stent graft with a suprarenal aortic extension. This publication follows the U.S. Food and Drug Administration (FDA) approval of the device and treatment algorithm in 2009, and recent FDA and European CE Mark approvals of the PowerFit suprarenal aortic extension this year.

John McDermott, President and Chief Executive Officer said, "We are pleased to announce these excellent results from our suprarenal trial, which build on the similar published results from our original FDA trial, and the Powerlink XL trial. These results further support the recent launch of our PowerFit Aortic Extension, which continues to receive very positive physician feedback. As the shift from open surgery to endovascular repair evolves, we expect to continue to benefit from being the only company that offers physicians both infrarenal and suprarenal configurations along with the unique advantages of the anatomical fixation technique."

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company’s flagship product is the Powerlink(R) System, which is an endovascular stent graft for the treatment of abdominal aortic aneurysms (AAA). AAA is a weakening of the wall of the aorta, the largest artery in the body, resulting in a balloon-like enlargement. Once AAA develops, it continues to enlarge and, if left untreated, becomes increasingly susceptible to rupture. The overall patient mortality rate for ruptured AAA is approximately 75%, making it a leading cause of death in the U.S. Additional information can be found on Endologix’s Web site at www.endologix.com.

Forward-Looking Statements

Except for historical information contained herein, this news release contains forward-looking statements, the accuracy of which are necessarily subject to risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Endologix. Many factors may cause actual results to differ materially from anticipated results, including the success of sales efforts for the Powerlink System and related new products, product research and development efforts, and other economic, business, competitive and regulatory factors. The Company undertakes no obligation to update its forward looking statements. Please refer to the Company’s Annual Report on Form 10-K for the year ended December 31, 2009, and the Company’s other filings with the Securities and Exchange Commission, for more detailed information regarding these risks and other factors that may cause actual results to differ materially from those expressed or implied.