Endologix Completes Enrollment in PEVAR Randomized Trial

IRVINE, Calif., Feb. 9, 2012 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today the completion of patient enrollment in the Company’s prospective, multicenter, randomized clinical trial of a bilateral percutaneous approach to endovascular abdominal aortic aneurysm repair (EVAR). Endologix is the first Company to receive United States Food and Drug Administration (FDA) approval of an Investigational Device Exemption (IDE) to evaluate percutaneous EVAR (PEVAR) for the treatment of abdominal aortic aneurysms (AAAs). The Company expects to submit a supplement to its premarket approval application (PMA) with the primary endpoint results to request FDA approval for this broadened PEVAR indication during the second quarter of 2012.

John McDermott, Endologix President and Chief Executive Officer, said, “The completion of enrollment in our PEVAR clinical trial is an important milestone for our new product pipeline. It clearly positions Endologix to be the first and only Company to receive a totally percutaneous indication for EVAR and to be able to train physicians on the PEVAR procedure. The results from the roll-in phase of the trial were very promising with 95% technical success and an average 1.7-day length of hospital stay, supporting our belief that physicians and patients will be attracted to this less invasive procedure.”

The percutaneous EVAR (PEVAR) clinical trial is designed to support the safety and effectiveness of the Company's IntuiTrak™ endovascular delivery system and Powerlink® family of stent grafts in the percutaneous treatment of AAA. The clinical trial incorporates a “pre-close” technique facilitated by the Prostar® XL Percutaneous Vascular Surgical System or Perclose ProGlide® Suture-Mediated Closure System, both made by health care company Abbott. This multi-center, prospective, randomized clinical trial enrolled 191 patients (41 roll-in patients and 150 randomized patients) at 20 U.S. clinical sites. In the randomized arm of the study, 100 patients underwent percutaneous EVAR with closure facilitated by either the Prostar XL or Perclose ProGlide device, and 50 patients underwent standard EVAR, which required an open surgical cut-down of one or both femoral arteries for delivery system access and device deployment.

Since receiving FDA approval of the IDE, the Company has integrated the IntuiTrak™ delivery system and Powerlink® stent grafts into a single next-generation platform, the AFX™ Endovascular AAA System, which was launched in August 2011. The AFX system features several enhancements, including a lower profile introducer sheath that the Company expects will further facilitate the percutaneous EVAR procedure upon regulatory approval.

About Endologix, Inc.

Endologix, Inc. (the “Company”) develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is endovascular stent grafts 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 relating to the outcome of the PEVAR clinical trial, 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 uncertainties related to the development and clinical testing of new products. 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, 2010, 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.

CONTACT: COMPANY CONTACT:

Endologix, Inc.

John McDermott, CEO

(949) 595-7200
INVESTOR CONTACTS:

The Ruth Group

Nick Laudico (646) 536-7030

Zack Kubow (646) 536-7020

Source: Endologix

News Provided by Acquire Media