Endologix Receives IDE Approval for the Ventana(TM) Fenestrated Stent Graft System

IRVINE, Calif., Sept. 6, 2011 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of minimally invasive treatments for aortic disorders, announced today that it has received Investigational Device Exemption ("IDE") conditional approval from the United States Food and Drug Administration ("FDA") to begin U.S. clinical trials to evaluate the Ventana™ Fenestrated Stent Graft System for the endovascular repair of juxtarenal and pararenal aortic aneurysms. Endologix expects to begin enrolling patients at a few centers in the U.S. before the end of this year.

The Ventana™ device is a new aortic extension designed to be used with the AFX® Endovascular AAA System and Xpand™ renal stent grafts. The AFX system is commercially available in the U.S. and expected to be available in other international markets in 2012. The Ventana™ and Xpand™ stent grafts are not approved for marketing in the U.S. or abroad and are restricted to investigational use only.

U.S. National Principal Investigator Daniel G. Clair, MD (Chairman, Department of Vascular Surgery, Cleveland Clinic Foundation, Cleveland, OH) commented, "The initial clinical experience with Ventana outside of the U.S. has been very positive. International results demonstrate proof of concept for this innovative system, which is the first off-the-shelf endovascular option for patients with juxtarenal and pararenal aortic aneurysms. On behalf of the Ventana IDE investigators, we look forward to initiating the clinical program in the U.S. and furthering the research efforts on this promising technology."

John McDermott, President and Chief Executive Officer said, "We are delighted to receive the U.S. FDA conditional IDE approval, and are encouraged by the initial positive outcomes with Ventana in clinical studies outside the U.S. It is estimated that 20% of diagnosed abdominal aortic aneurysms are not treatable with currently approved endovascular devices. Ventana potentially provides these patients with an innovative and less-invasive alternative to open repair. We look forward to collaborating with the Ventana clinical investigators on the IDE trial and are hopeful to provide a new endovascular therapy for patients with complex aortic aneurysms in the years ahead."

About Endologix, Inc.

Endologix, Inc. 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 clinical program for the Ventana Fenestrated Stent Graft System and Xpand renal stent grafts, 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: Endologix, Inc.

John McDermott, CEO

(949) 595-7200

www.endologix.com
INVESTOR CONTACTS:

The Ruth Group

Nick Laudico (646) 536-7030

Zack Kubow (646) 536-7020

Source: Endologix

News Provided by Acquire Media