Endologix Announces First Patient Treated in Ventana™ U.S. Clinical Trial

IRVINE, Calif., Jan. 31, 2012 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that the first patient has been enrolled in the Company's U.S. clinical trial to evaluate the Ventana™ Fenestrated Stent Graft System for the endovascular repair of juxtarenal and pararenal abdominal aortic aneurysms (AAAs). The procedure was performed by Matthew Eagleton, MD (Cleveland Clinic Foundation, Department of Vascular Surgery). National Principal Investigator Daniel G. Clair, MD (Chairman, Department of Vascular Surgery, Cleveland Clinic Foundation) proctored the procedure.

Dr. Eagleton said, "We are excited to be the first investigational site to enroll a patient in the Ventana trial using this innovative new stent graft technology. This trial will offer participation to patients with abdominal aortic aneurysms that extend near or involve the renal arteries — patients who are not treatable with any of the approved endovascular aneurysm repair devices. The Ventana stent graft is designed with movable fenestrations for in vivo adjustment to match the specific location of a patient's renal arteries along the aorta, which is essential to addressing the anatomical challenges of these aneurysms. The Ventana system performed well and post-procedure imaging showed that the stent graft completely sealed the aneurysm and maintained blood flow to the kidneys."

Dr. Clair added, "The Ventana system is the first integrated, off-the-shelf endovascular stent graft device system in a multicenter, prospective clinical trial for patients with juxtarenal and pararenal AAAs. The experience with our first Ventana patient in the U.S. highlighted the fenestration movement, ease of use, and aneurysm sealing attributes of the device and, more importantly, provided a minimally invasive treatment option for a patient that previously could not be offered an approved endovascular option. We look forward to begin treating patients at other clinical trial sites in the near future."

The multicenter, prospective, single arm Ventana clinical trial was approved by the U.S. Food and Drug Administration under an Investigational Device Exemption (IDE) for conduct at up to 25 U.S. clinical sites and involving 122 patients. The trial is intended to support a future premarket approval (PMA) application to the FDA to provide reasonable assurances of safety and effectiveness for the Ventana System for the endovascular repair of juxtarenal and pararenal aneurysms in selected patients. The trial primary endpoints will evaluate safety (major adverse events) at 30 days and effectiveness (treatment success) at one year, with continuing follow-up to five years.

John McDermott, President and Chief Executive Officer, said, "Enrolling the first patient in our Ventana U.S. clinical trial is another key milestone in the path towards bringing this important technology to patients in the U.S. The international clinical experience with Ventana demonstrates that it has the potential to be the only off-the-shelf EVAR system to address approximately 20% of AAA patients who have juxtarenal or pararenal aneurysms."

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. The Ventana™ Fenestrated Stent Graft System is an investigational device.

Forward-Looking Statements

Except for historical information contained herein, this press 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.
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