Endologix Announces Enrollment of First Patient in EVAS FORWARD-IDE Clinical Trial

IRVINE, Calif., Jan. 21, 2014 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that the first patient was treated in the EVAS FORWARD-IDE clinical trial, the Company's pivotal clinical trial to evaluate the safety and effectiveness of the Nellix® EndoVascular Aneurysm Sealing System ("Nellix EVAS System") for the endovascular repair of infrarenal abdominal aortic aneurysms. The EVAS FORWARD-IDE clinical trial is approved to enroll 180 patients at up to 30 centers in the U.S., Canada and Europe, of which approximately 25 will be in the U.S. The first procedure was performed by Professor Dittmar Boeckler, MD, a vascular surgeon at Heidelberg University Hospital in Germany.

Professor Boeckler commented, "The Nellix EVAS System is a breakthrough in endovascular aneurysm treatment. Sealing the entire aneurysm sac with the Nellix system effectively excludes the aneurysm sac and more closely mimics what we do in open surgical procedures, but without the associated risks. It is an important advance in endovascular AAA treatment with the potential to reduce post procedural re-interventions. Our results to date have been very encouraging and we are pleased to have the first patient enrolled in this pivotal study. The Nellix EVAS System performed as we expected; effectively sealing the patient's aneurysm with a simple and predictable endovascular procedure."

The Nellix EVAS system is a new generation of abdominal aortic aneurysm ("AAA") therapy designed to seal the entire aneurysm. Nellix is the first and only EVAS product and was developed to simplify procedures, reduce re-interventions and expand the treatable patient population. Endologix received CE Mark for the Nellix EVAS System in the first quarter of 2013 and the limited commercial release of the product in Europe is currently underway.

The EVAS FORWARD-IDE is one of a number of clinical studies that make up the broader EVAS FORWARD Clinical Program aimed at establishing clinical and economic evidence for EVAS using Nellix.

John McDermott, Chairman and Chief Executive Officer for Endologix, said, "The beginning of enrollment in the EVAS FORWARD-IDE clinical trial is a positive milestone for the Company as we continue to expand our innovative portfolio of endovascular aortic devices. The experience in the first IDE procedure matched our expectations based on our international clinical trial results and early commercial results in Europe. Based on the anticipated enrollment timeline and one-year follow up period, the Nellix EVAS System could potentially be available to physicians and patients in the U.S. by the end of 2016."

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The company's primary 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 website at www.endologix.com.

Forward Looking Statements

Except for historical information contained herein, this news release contains forward-looking statements, including statements with respect to the of the EVAS FORWARD-IDE clinical trial, the clinical performance of the Nellix EVAS System, the regulatory process, and clinical and commercial acceptance of the Nellix EVAS System, the accuracy of which are necessarily subject to risks and uncertainties, which are difficult or impossible to predict accurately and some of which are beyond the control of Endologix. Many factors may cause actual results to differ materially from anticipated results, including availability of subjects and the timing of enrollment for the clinical trial, the performance of the product under development, the acceptability of data by regulatory authorities and uncertainties in the acceptance of EVAS procedures by physicians and payers. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. The Company undertakes no obligation to update any forward looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events. Please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, 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.
Endologix, Inc.

John McDermott, CEO
Shelley Thunen, CFO
(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