Endologix Receives IDE Approval for the Nellix(R) EndoVascular Aneurysm Sealing System

IRVINE, Calif., Dec. 20, 2013 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that it has received Investigational Device Exemption (“IDE”) approval from the United States Food and Drug Administration (“FDA”) to begin a pivotal clinical trial to evaluate the safety and effectiveness of the Nellix® EndoVascular Aneurysm Sealing System (“EVAS”) for the endovascular repair of infrarenal abdominal aortic aneurysms. The study, 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. The EVAS FORWARD-IDE study is approved to enroll 180 patients at up to 30 sites in the U.S., Canada and Europe.

The Nellix EVAS system is a new generation of abdominal aortic aneurysm (“AAA”) therapy designed to seal the entire aneurysm with a biocompatible polymer. 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 commercial release of the product in Europe is currently underway.

Jeffrey Carpenter, MD., Chairman and Chief of Surgery for Cooper University Health Care in New Jersey, is the study's National Principal Investigator. Dr. Carpenter stated, “The unique ability of Nellix to seal the entire aneurysm sac is breakthrough technology and is the first meaningful advancement in AAA repair since endovascular grafts were introduced back in the late 1990s. We believe Nellix has the potential to dramatically change the way we treat AAA.”

John McDermott, Chairman and Chief Executive Officer for Endologix, said, "We are pleased to receive IDE approval from the FDA to begin this important clinical trial and look forward to collaborating with the investigators on this exciting new product. We believe Nellix has the potential to improve outcomes for patients and simplify AAA procedures for physicians. Based on the anticipated enrollment timeline and one-year follow up period, Nellix could potentially be available to physicians and patients in the U.S. in the second half 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 commencement 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.

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