Endologix Completes Patient Enrollment in the Nellix(R) EVAS FORWARD-IDE Clinical Trial

Primary Endpoint Results to Support Future PMA Application for Nellix in the U.S. and Other International Markets

IRVINE, Calif., Nov. 18, 2014 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that it has completed patient enrollment in the EVAS FORWARD-IDE clinical trial, the Company's U.S. pivotal clinical trial designed 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 ("AAA"). Primary endpoint analysis results at one-year and beyond will be used to support the Company's premarket approval (PMA) application to the U.S. Food & Drug Administration (FDA) for the Nellix EVAS System.

Jeffrey Carpenter, MD., Professor and Chairman of Surgery for Cooper Medical School and Chief of Surgery for Cooper Health System in New Jersey, and National Principal Investigator of the EVAS FORWARD-IDE clinical trial, stated, "The Nellix IDE clinical trial is the first study to examine the safety and effectiveness of EVAS in patients in the United States. Nellix has the potential to be a breakthrough technology for the treatment of AAA because it is the only device that directly targets the primary cause of secondary interventions by sealing the entire aneurysm sac. We look forward to monitoring the trial patients during the follow-up period and remain optimistic that Nellix will improve patient outcomes and enable physicians to treat more patients in the future."

The EVAS FORWARD-IDE clinical trial enrolled 179 patients at 29 centers in the U.S. and Europe. Enrollment under an extended investigation phase is anticipated to begin shortly and will continue during the pivotal trial follow-up period and PMA preparation/review process. Based on current assumptions and timelines, the company anticipates FDA approval of the Nellix System in the U.S. before the end of 2016.

Robert Cuff, MD, a vascular surgeon with Spectrum Health in Grand Rapids, Michigan and leading enroller in the Nellix pivotal trial said, "EVAS with Nellix holds the promise of being a significant advancement in the treatment of AAA. In the cases performed at our site, we found the Nellix procedure to be simple, predictable and with good acute outcomes. Based upon our results so far, we expect that Nellix will significantly reduce endoleaks and provide meaningful clinical benefits for patients. We look forward to participating in the Continued Access phase of the IDE and offering Nellix to patients when it is commercially available in the U.S."

John McDermott, Chairman and Chief Executive Officer of Endologix, said, "The completion of enrollment in the Nellix pivotal trial is another important milestone as we work to bring this groundbreaking technology to patients in the U.S. We are already experiencing strong adoption of Nellix in Europe and the physician enthusiasm in the U.S. is equally positive, giving us confidence in the long-term potential of EVAS with Nellix to be an important new solution for patients with AAA."

The Nellix EVAS System is a new generation of abdominal aortic aneurysm ("AAA") therapy designed to seal the entire aneurysm and improve patient outcomes. Nellix is the first and only EVAS device and was developed to simplify procedures, minimize endoleaks, 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 introduction of the product in Europe is currently underway. The Nellix EVAS System is approved for clinical trial use only in the U.S. and is not approved in the U.S. for commercial use.

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. Endologix 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 80%, making it a leading cause of death in the U.S. Additional information can be found on Endologix's website at www.endologix.com.

Cautions Regarding Forward-Looking Statements
Except for historical information contained herein, this news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to continuing clinical trials, anticipated clinical outcomes, regulatory approvals and healthcare provider acceptance of the Nellix EVAS System, 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 ability of the Company to recruit hospitals and surgeons to participate in the study and their ability to enroll patients, and other technical and clinical factors. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Endologix 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 Endologix’s Annual Report on Form 10-K for the year ended December 31, 2013, and Endologix’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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