Endologix Announces Promising Early Clinical Data From the Nellix EVAS FORWARD-IDE Clinical Study

30-Day Results From Pivotal Trial Presented at the SVS 2015 Annual Meeting

IRVINE, Calif., June 17, 2015 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today the presentation of 30-day outcomes for the pivotal cohort from the Company-sponsored investigational device exemption (IDE) clinical investigation, the EVAS FORWARD-IDE Study (www.clinicaltrials.gov, NCT01726257). This multicenter, prospective, single arm clinical study is 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”). The study primary endpoints are major adverse events at 30 days (safety), and Treatment Success at one year (effectiveness). Jeffrey P. 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 study, presented on behalf of the study investigators at the Society for Vascular Surgery 2015 annual meeting in Chicago. The Nellix EVAS System is approved only for investigational use in the U.S. and is commercially available in Europe and select other international markets.

The EVAS FORWARD-IDE clinical study enrolled eligible patients with AAA at 29 centers in the U.S. and Europe. After enrolling the first patient, each site enrolled patients to comprise the 150-patient pivotal cohort between February and November 2014. Protocol-defined follow-up at one month, six months, one year, and annually thereafter to five years includes a clinical assessment and high resolution computed tomography angiographic (CTA) scan with core laboratory assessment for the presence of endoleaks, occlusion, migration, aneurysm stability and device integrity.

Key highlights from the presentation include:

- 100% procedural technical success with few device-related serious adverse events
- Median fluoroscopy and procedure times of 10 minutes and 87 minutes, respectively.
- Low 30-day mortality (0.7%) and overall major adverse events (2.7%) as adjudicated by an independent Clinical Events Committee, with no aneurysm rupture or conversion to open repair.
- Low incidence of any endoleak on the 1-month CTA scan (6%).
- No lumen thrombosis or occlusions or other device integrity issues

Based on current assumptions and timelines, the Company anticipates submission of the premarket approval (PMA) application to the U.S. FDA in early 2016, and is anticipating FDA approval of the Nellix System by the end of 2016.

Dr. Carpenter commented, "I applaud the study investigators for their high degree of engagement in rapidly completing enrollment and in their careful attention to detail in this first US multicenter experience with this new EVAS technology. The pivotal cohort procedural outcomes support the applicability and predictability of the Nellix EVAS procedure for patients with AAA. We are encouraged by the early results, and we look forward to completing the 1-year follow-up. Like many of our fellow investigators, we intend to continue enrolling patients in the continued access arm of the study to further build on the growing clinical evidence for the EVAS technology."

The Nellix EVAS System is a new generation of AAA therapy designed to seal the entire aneurysm sac. It is the first and only EVAS technology in clinical trials in the U.S. John McDermott, Chairman and Chief Executive Officer of Endologix, said, "We thank Dr. Carpenter and the study investigators for their strong support of the IDE study, and their continued efforts to build the clinical data for the Nellix EVAS System. There is significant worldwide interest in the Nellix EVAS technology and we look forward to being able to offer this technology to physicians and patients with AAA in the U.S. and other markets around the world."

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 70%, 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 continued enrollment of patients and timing for completion of the study, the submission to and potential approval by the FDA, and the broad availability 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 difficulties in maintaining patient follow-up over a long-term and unanticipated clinical outcomes. 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, 2014, and Endologix’s subsequent 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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