Endologix to Initiate First Ever Comparative Randomized EVAR Study

LEOPARD Study to Enroll 600 Patients to Provide a "Real-World" Head-to-Head Comparison of the AFX® System Versus Other Commercially Available EVAR Devices

IRVINE, Calif., Sept. 29, 2014 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that it will conduct the first ever prospective randomized clinical study to compare outcomes in endovascular repair of abdominal aortic aneurysms (EVAR). The LEOPARD Study (Looking at EVAR Outcomes by Primary Analysis of Randomized Data) has been designed to provide an accurate and unbiased assessment of commercially available EVAR devices with a planned enrollment of 600 patients.

Christopher J. Kwolek, MD, Director, Vascular and Endovascular Training program at the Massachusetts General Hospital and Chief of Vascular Surgery at Newton Wellesley Hospital in Boston and the National Principal Investigator for the LEOPARD Study, said, "LEOPARD is a landmark study that is intended to produce the highest level of clinical evidence. I applaud Endologix for supporting a head-to-head real-world comparison of commercially available devices here in the United States. The primary analysis will compare Endologix's AFX® Endovascular AAA System against an equally matched control population of other commercially available EVAR devices. Results from LEOPARD will help shape EVAR treatment decisions and technology development in order to provide the best possible outcomes for our patients."

LEOPARD will include up to 60 active EVAR centers throughout the United States. The primary endpoint of the study is treatment success at one year based upon: procedural success; and rates of freedom from aneurysm rupture; conversion to open surgical repair; endoleaks; clinically significant device migration; aneurysm enlargement and secondary endovascular procedures. Results from the study will be independently adjudicated by a third-party. The follow-up period will be five years.

The steering committee for the LEOPARD study includes:

- Christopher Kwolek, MD, Director, Vascular and Endovascular Surgery Training Program, Massachusetts General Hospital, Chief of Vascular Surgery at Newton Wellesley Hospital, in Boston (National Principal Investigator)
- Benjamin Starnes, MD, Professor of Surgery and Chief of the Vascular Surgery Division, University of Washington (Steering Committee Chairman)
- Daniel Clair, MD, Chairman of Vascular Surgery, Cleveland Clinic
- Mark Fillinger, MD, Director, Vascular Surgery Training Programs, Professor of Surgery, Geisel School of Medicine, Dartmouth
- Tom Maldonado, Associate Professor of Surgery, New York University Langone Medical Center, Chief of Vascular Surgery, Manhattan VA Hospital
- Timothy Sullivan, MD, Chairman, Vascular/Endovascular Surgery, Minneapolis Heart Institute at Abbott Northwestern Hospital
- Frank Veith, MD, Professor of Surgery, Cleveland Clinic and New York University

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 the anticipated number of sites and patient enrollment in the LEOPARD study, and the ability of the data arising from the LEOPARD study to shape EVAR treatment decisions and technology development, 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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