

Endologix Reports Positive Clinical Data from the Nellix EVAS FORWARD-IDE Study

EVAS FORWARD-IDE Meets Primary and Secondary Endpoints; Additional Data to be Presented at SVS Meeting on June 11

IRVINE, Calif., May 26, 2016 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today positive clinical data from the Nellix investigational device exemption (IDE) clinical trial, the EVAS FORWARD-IDE Study (<u>www.clinicaltrials.gov</u>, 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 data from the EVAS FORWARD-IDE study demonstrated that the Nellix EVAS System met the study primary endpoints for major adverse events at 30 days (safety) and Treatment Success at one year (effectiveness).

The key highlights from the EVAS FORWARD-IDE study clinical data include:

- 1 150 patients in the pivotal cohort were treated at 30 centers in the US and Europe between January and November 2014.
- 100% procedural technical success achieved.
- The major adverse event (MAE) rate at 30-days was 2.7%, achieving the primary safety endpoint and comparing positively to the Society for Vascular Surgery (SVS) open surgical repair control group rate of < 56%.
- At one year, the treatment success rate was 94%, achieving the primary effectiveness endpoint and comparing favorably to the performance goal of > 80%.
- Freedom from all-cause mortality and AAA-related mortality were 96% and 99% respectively.
- Freedom from device related secondary interventions was 96.6%, the highest rate ever reported for an IDE study of an endovascular AAA device.
- Endoleaks were present in 3.1% of patients at 1-year, the lowest rate ever reported for an IDE study of an endovascular AAA device.

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, said, "We are very pleased to report that the EVAS FORWARD-IDE Study met its primary safety and effectiveness endpoints. The 1-year results are highly encouraging and demonstrate that low overall endoleaks can reduce secondary interventions. This is an important milestone towards achieving FDA approval and making the Nellix aneurysm sealing technology available to AAA patients in the United States."

The Nellix EVAS System is a new generation of AAA therapy designed to seal the entire abdominal aortic aneurysm sac. It is the first and only EVAS product and was developed to reduce all types of endoleaks and improve long-term patient outcomes. Nellix is an investigational device in the United States.

The results from the EVAS FORWARD-IDE Study were submitted to the U.S. Food and Drug Administration as part of the Company's premarket approval (PMA) submission for Nellix EVAS System. The Company remains on track to receive potential FDA approval for the Nellix EVAS System at the end of 2016 or early 2017.

The positive clinical data from the EVAS FORWARD-IDE Study was just published in the schedule of the upcoming 2016 Vascular Annual Meeting of the Society for Vascular Surgery (SVS), which is taking place from June 8-11, 2016 in National Harbor, Maryland. Dr. Carpenter will present the full results from EVAS FORWARD-IDE Study on the morning of Saturday, June 11, 2016 at the SVS meeting and will participate in a conference call and webcast hosted by Endologix at 1:00 pm ET that day to present the results. The webcast will include presentation slides to accompany the prepared remarks, which will be followed by a question and answer session. The conference call will be available to interested parties through a live audio webcast at <u>investor.endologix.com</u>, where it will be archived and accessible for approximately 12 months. The webcast will include presentation slides to accompany the conference call. The live dial-in number for the call is 877-407-0789 (U.S.) or 201-689-8562 (International), which should be used by those interested in participating in the question and answer session. A telephonic replay of the call will be available from June 11, 2016 to June 18, 2016. The replay dial in numbers are 877-870-5176 (U.S.) or 858-384-5517 (International). The replay pin number is 13637957.

Forward-Looking Statements

This communication includes statements that may be "forward-looking statements" within the meaning of the Private

Securities Litigation Reform Act of 1995, including with respect to the clinical and commercial potential, and U.S. regulatory approval, 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 unanticipated clinical outcomes and delays in the regulatory approval process. 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, 2015, 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.

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company's 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.

COMPANY CONTACT:

Endologix, Inc.

John McDermott, CEO

Vaseem Mahboob, CFO

(949) 595-7200

www.endologix.com

INVESTOR CONTACTS:

The Ruth Group

Nick Laudico (646) 536-7030

Zack Kubow (646) 536-7020

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