



Endologix Reports Positive 1-Year Results from the Ovation® LUCY Study

June 28, 2018

Presented in Late-Breaking Session at the Society for Vascular Surgery Annual Meeting

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 28, 2018-- Endologix, Inc. (Nasdaq:ELGX), a developer and marketer of innovative treatments for aortic disorders, announced 1-year results from the LUCY (Evaluation of Female Candidates for Abdominal Aortic Aneurysm Repair) registry as reported on Saturday, June 23rd at the 2018 Society for Vascular Surgery Annual Meeting. The LUCY study is the first to prospectively evaluate endovascular aneurysm repair (EVAR) outcomes in women who have more complex aortic anatomy and, subsequently, have worse reported outcomes than men undergoing EVAR.¹ The results of the LUCY 1-year data expand on the 30-day results presented last year, showing that at least 28% more women are eligible for minimally-invasive EVAR when using the Ovation Abdominal Stent Graft System than when using other EVAR systems.²

The LUCY study is a prospective, consecutively enrolling, non-randomized, multi-center, post-market registry evaluating the Ovation System for the endovascular treatment of abdominal aortic aneurysms (AAA) in women.³ The study enrolled a total of 225 patients, including 76 females in the treatment group and 149 males in the control group, at 39 sites in the U.S. The primary endpoint of the study was the 30-day Major Adverse Event ("MAE") rate and secondary endpoints including serious and non-serious adverse events through one year.

The 1-year LUCY data showed that, despite having more complex anatomy at the time of the index procedure than men, women had similar outcomes to men following treatment with the ultra-low profile (14F) Ovation device:

- Freedom from AAA-related mortality: 100% in women vs 98.6% in men
- Freedom from reintervention for Type 1a endoleak: 98.6% in women vs 97.9% in men
- Freedom from rupture: 100% in both women and men
- Freedom from conversion: 100% in both women and men
- Freedom from all device-related reintervention: 97.2% in both women and men

Jennifer Ash, M.D., Christie Clinic Vein and Vascular Center and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Champaign, said, "Women have specific anatomical challenges in iliac access and proximal aortic neck morphology and have historically had worse outcomes from EVAR than men. The results of the LUCY study suggest that the unique features of the low-profile Ovation system may overcome these challenges and achieve similar outcomes in men and women."^{4,5}

John Onopchenko, Chief Executive Officer of Endologix, Inc., commented, "We are excited to have completed follow-up on the LUCY study and are pleased that the one-year results suggest, for the first time in a prospective study, that female AAA patients can be treated with EVAR as effectively as men, when using the Ovation System. LUCY's evidence provides physicians with new information to confidently engage female patients with prospectively derived outcomes previously realized only by male patients."

The LUCY study was led by an advisory board whose members include: Chairperson Jennifer Ash, M.D., Christie Clinic Vein and Vascular Center and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Champaign; Venita Chandra, M.D., Clinical Assistant Professor of Surgery-Vascular Surgery, Stanford School of Medicine; Monica Hunter, M.D., Birmingham Heart Clinic at St. Vincent's Birmingham; Eva Ruzicidlo, M.D., McLeod Vascular and Associate Professor of Surgery, Geisel School of Medicine, Dartmouth; and Ageliki Vouyouka, M.D., Associate Professor of Surgery and Radiology, Mount Sinai Hospital.

1. Pinar Ulug, PhD, et al. www.thelancet.com Published online April 25, 2017 Sweet, M, M.D., et al. *J Vasc Surg* 2011; 54:931-7. Analysis based on available data from the LUCY Study female cohort (72 out of 76) and on comparisons with grafts ranging from 18F – 21F OD
2. manufactured by global market leaders. Data extracted on May 1, 2017. The Ovation Abdominal Stent Graft System has not been studied in a head-to-head clinical study against other EVAR devices for outcomes in women.
3. 2% of patients had vascular characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness, of Ovation when used off-IFU, have not been established.
4. Mehta M, Byrne WJ, Robinson H, et al. "Women derive less benefit from elective endovascular aneurysm repair than men." *J Vasc Surg. Apr* 2012;55(4):906-913.
5. Lowry, D, et al. "Sex-related Outcome Inequalities in Endovascular Aneurysm Repair." *Eur J Vasc Endovasc Surg* (2016) 1-8.

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 United States. For more information, visit www.endologix.com.

Cautions Regarding Forward-Looking Statements

Except for historical information contained herein, this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “could,” “may,” “will,” “believe,” “estimate,” “forecast,” “goal,” “project,” “continue,” “outlook,” “guidance,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements used in this press release include, but are not limited to, statements regarding the Ovation System’s possible expansion of EVAR eligibility, and other possible benefits of Endologix’s Ovation System, the accuracy of which are necessarily subject to risks and uncertainties that may cause future events to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ materially and adversely include: future availability and sufficiency of data supporting the benefits of Endologix’s Ovation System; risks regarding the conduct of Endologix’s clinical trials, studies and registries involving the Ovation System, including the results thereof; risks regarding quality systems operations and outcome of third party audits of such systems; risks regarding acceptance, endorsement and use of Endologix’s Ovation and other products; risks associated with the manufacturing of Endologix’s Ovation and other products; risks relating to Endologix’s product research and development efforts; regulatory risks, including uncertainty in the process of obtaining and maintaining U.S. FDA and other regulatory approvals for the Ovation System; Endologix’s ability to access equity and debt capital on acceptable terms; Endologix’s ability to enter into or maintain existing financing arrangements on acceptable terms; risks associated with international operations, including currency exchange rate fluctuations; Endologix’s ability to protect its intellectual property rights and proprietary technologies; and other economic, business, competitive and regulatory factors. Undue reliance should not be placed upon the forward-looking statements contained in this press release, which speak only as of the date of this press release. Endologix undertakes no obligation to update any forward-looking statements contained in this press release 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 filings with the Securities and Exchange Commission including its Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent Quarterly Reports on Form 10-Q, for more detailed information regarding these risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied.

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