Endologix Reports Positive Clinical Data from the Ovation LUCY Study

First Prospective Clinical Trial to Evaluate Endovascular Aneurysm Repair (EVAR) in Women

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (Nasdaq:ELGX), a developer and marketer of innovative treatments for aortic disorders, today announced 30-day results from the LUCY (Evaluation of Females who are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair) study. The data showed that at least 28% more women became eligible for minimally-invasive endovascular aneurysm repair (EVAR) when using the Ovation® Abdominal Stent Graft System. The Ovation System is designed to better suit female anatomy than traditional EVAR options and demonstrated lower mortality and complications when compared to previous EVAR studies. The LUCY study is the first to specifically evaluate EVAR outcomes in women, who have historically been underrepresented in EVAR clinical trials.

Recent clinical articles in The Lancet and the Journal of Vascular Surgery indicate that aneurysms grow faster in women than men, leading to a higher rate of rupture and death. Female anatomy may also be more challenging for most commercial EVAR treatments, leading to less eligibility for EVAR and greater mortality, major complications, and readmissions, when compared to men.

The 30-day LUCY data showed that, in women, the ultra-low profile (14F) Ovation device resulted in:

- At least 28% greater EVAR eligibility for women with AAA
- 1.3% major adverse events, the lowest rate reported for EVAR, compared to other contemporary, prospective, post-market registries
- No deaths
- No proximal endoleaks
- No limb occlusion
- Low readmission rate of 3.9%
- 100% procedural success

Marc Schermerhorn, MD, Associate Professor of Surgery, Beth Israel Deaconess Medical Center, said, “Analysis of historical EVAR clinical data is showing us a large unmet need for AAA treatments for women. Women are less prone to develop the disease, but, when they do, they have significantly worse outcomes than men. New treatment options that better accommodate female anatomy, thereby increasing access and improving outcomes, may go a long way in rectifying the gender disparity in AAA treatment.”

Venita Chandra, MD, Clinical Assistant Professor of Surgery-Vascular Surgery, Stanford School of Medicine, said, “It is gratifying to see better early outcomes for women in the LUCY study. The Ovation device was able to accommodate the particular challenges of female anatomy, such as small access vessel diameter, short neck length, and higher neck angulation. In addition, mortality, major adverse events, and readmissions were improved for both sexes. I look forward to assessing the durability of these results over the longer term.”

The LUCY study was a prospective, consecutively enrolling, non-randomized, multi-center, post-market registry evaluating the Ovation Platform for the endovascular treatment of AAA in women. 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. Longer-term data from the LUCY study will be shared after the one-year follow-up.

John McDermott, Chief Executive Officer of Endologix, commented, "We are very pleased with the early LUCY study results, which demonstrate the potential Ovation offers to enable more effective treatment of female AAA patients and significantly improved outcomes for all patients. We look forward to expanding Ovation's access to more women in those regions where it is available, and to educating both the clinical community and patients about the unique needs of the female patient and the treatment options that are optimized for them."

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

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.

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 results of ongoing clinical trials and the commercial success of the Ovation platform, 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. 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, 2016, 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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