Endologix, Inc. Announces Enrollment of First Patients in ELEVATE IDE Clinical Study

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (Nasdaq:ELGX), a developer and marketer of innovative treatments for aortic disorders, announced today that the first patients were treated in the Expanding Patient Applicability with Polymer Sealing Ovation Alto Stent Graft (ELEVATE) IDE clinical study, the Company’s pivotal clinical trial to evaluate the safety and effectiveness of the Ovation Alto™ Abdominal Stent Graft System for the repair of infrarenal abdominal aortic aneurysms (AAAs). The ELEVATE IDE clinical trial is approved to enroll 75 patients at up to 12 centers in the U.S. The first procedure was performed by Dr. Steve Henao, Chief, Division of Vascular Surgery at New Mexico Heart Institute.

The study principal investigator, Dr. Sean Lyden, Chairman of the Department of Vascular Surgery at Cleveland Clinic commented, "We are excited to start treating patients in the ELEVATE IDE trial. The polymer technology in the device allows for active sealing in the aortic neck. The polymer sealing ring has proven durability in maintaining aneurysm exclusion to five years as reported in the Global Ovation Pivotal Trial. The repositioning of the sealing ring to 7mm below the top of the fabric will allow treatment of more challenging and complex anatomies in this trial."

Ovation Alto is the newest device in the Ovation® platform of abdominal stent graft systems, which has proven clinical results reported from the Ovation global pivotal trial and European Post-Market Registry. Ovation Alto expands EVAR to treat more patients on IFU. This is achieved by the conformable O-rings with CustomSeal™ polymer that have been repositioned near the top of the endograft, providing seal just below the renal arteries. The Ovation platform is the lowest profile FDA-approved EVAR device, and it has been used successfully in the treatment of over 12,000 patients worldwide. Ovation Alto is an investigational device and currently not approved in any market.

John McDermott, Chief Executive Officer of Endologix, Inc., said, "The first patients enrolled in the ELEVATE IDE represent an important milestone for the Company, as we continue to advance our portfolio of innovative technologies for the treatment of AAA. Ovation Alto is the only infrarenal EVAR device that addresses a broad range of patients on IFU, representing a meaningful market opportunity. When approved, we expect that it will have the broadest indication for use of all infrarenal EVAR devices. We would like to thank physicians worldwide for their design input and participation in the previous and new clinical studies. Based on the anticipated enrollment timeline, we continue to expect Ovation Alto could be available in the U.S. in 2019."

About Endologix, Inc., Additional Disclosures

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 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.

In addition to being the study principal investigator, Dr. Lyden is a consultant on other matters relating to the design, development, and use of endovascular stent graft for treatment of AAA, and receives compensation for such services.

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 continued enrollment in the clinical trial, clinical outcomes, anticipated product IFU, and the timeline for regulatory approval, 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 uncertainties in regulatory actions and timing. 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 filed on March 1, 2017, 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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