Endologix, Inc. Announces Enrollment of the First Patient in EVAS2 IDE Clinical Study of the Nellix® EndoVascular Aneurysm Sealing System

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (Nasdaq:ELGX), a developer and marketer of innovative treatments for aortic disorders, announced today that the first patient was treated in the EVAS2 IDE Confirmatory Clinical Study of the investigational Nellix® EndoVascular Aneurysm Sealing (EVAS) System by Sajjad M. Hussain, M.D., Chief of the Department of Vascular Surgery at St. Vincent Health and St. Vincent Heart Center of Indiana.

The Nellix System is an endovascular abdominal aortic aneurysm (AAA) therapy designed to seal the entire aneurysm. Nellix is the first and only EVAS product developed as an alternative treatment approach to traditional EVAR devices. The Nellix System has received a CE Mark and is commercially available in many markets, including the EU.

EVAS2 is an IDE-approved confirmatory clinical study, which is designed to evaluate the safety and effectiveness of the second-generation Nellix System and the refined Indications for Use (IFU). The study is approved to enroll up to 90 primary patients at 28 U.S. centers, with one-year follow-up data required for the Pre-Market Approval (PMA) application.

"We are excited to be part of this important trial studying the concept of total aneurysm sealing," said Jeffrey Carpenter, M.D., Professor and Chairman of Surgery for Cooper Medical School, Chief of Surgery for Cooper Health System in New Jersey, and principal investigator for the EVAS2 study. "The second-generation Nellix device, together with the refined IFU and our clinical learnings over the past few years, has the potential to improve outcomes for patients with abdominal aortic aneurysms."

John McDermott, Chief Executive Officer of Endologix, Inc. said, "We would like to congratulate Dr. Hussain and the clinical study team at St. Vincent Hospital for completing the first EVAS2 procedure in the confirmatory study. We look forward to collaborating with all of our investigators to achieve excellent clinical outcomes for patients and to complete enrollment in the study. Based on anticipated enrollment, follow-up, and typical regulatory review timelines, we continue to estimate a decision on our PMA by the end of 2020."

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 anticipated enrollment, progress and results of Endologix’s EVAS2 clinical study, Endologix’s ability to obtain regulatory approval of the Nellix System within currently anticipated timeframes, and potential benefits of the Nellix System, the accuracy of which are necessarily subject to risks and uncertainties that may cause Endologix’s actual results 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 from anticipated results include Endologix’s ability to continue integrating the businesses and operations of, and to realize the expected benefits of its merger with, TriVascular, market acceptance, endorsement and use of Endologix’s products (including market acceptance and adoption of the Nellix System), risks associated with the manufacturing of Endologix’s products, the success of clinical trials relating to Endologix’s products (including successful enrollment of, and the clinical results generated by, the EVAS2 clinical study), product research and development efforts, uncertainty in the process of obtaining and maintaining U.S. FDA and other regulatory approvals for the Nellix System on currently anticipated timelines or at all, 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, 2016 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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