

Endovascular Aneurysm Sealing (EVAS) with Nellix System Associated with Higher Survival than Traditional Endovascular Aneurysm Repair (EVAR) in New Study

Results Presented Today in Late-Breaking Aortic Trials Session at Charing Cross International Symposium

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (Nasdaq: ELGX), a developer and marketer of innovative treatments for aortic disorders, today announced the results of a study, which was presented by Marc Schermerhorn, M.D., Chief of Vascular Surgery at Beth Israel Deaconess Medical Center, on the podium at the Late-Breaking Aortic Trials Session during the Charing Cross (CX) 40th International Symposium. This retrospective, propensity-weighted study compares long-term survival for the Nellix® EndoVascular Aneurysm Sealing (EVAS) System with traditional endovascular aneurysm repair (EVAR). The study demonstrated significantly higher three-year survival for EVAS patients. Those patients with larger aneurysms treated with EVAS had half the mortality at three years as compared to those treated with traditional EVAR systems.

The retrospective study included 333 EVAS patients from the original Nellix U.S. Investigational Device Exemption (IDE) Trial and 15,431 EVAR patients from the Society for Vascular Surgery Vascular Quality Initiative (VQI), all of whom were treated between 2014 and 2016. The patients were propensity weighted for abdominal aortic aneurysm (AAA) size, patient demographics, and cardiovascular risk factors. The primary outcome was overall survival, with a secondary analysis of overall survival stratified by aneurysm size.

EVAS patients experienced higher three-year survival than EVAR patients (93 percent versus 88 percent, P = .02), which corresponded to a 41-percent lower risk of mortality with EVAS. In patients with larger aneurysms (greater than 5.5cm in diameter), patients treated with EVAS had a mortality rate 50 percent lower than patients treated with EVAR (P = .02).

"The study sought to examine two different therapies for treating AAA and compare the associated mortality. Traditional EVAR excludes the aneurysm sac and has been associated with thrombus generation, sac remodeling, inflammation, and endoleaks, while EVAS excludes and seals the entire aneurysm sac," said Dr. Schermerhorn.

He continued, "The survival difference seen in this study supports the continued development of EVAS therapy and demonstrates its potential to improve patient outcomes. The results also justify further study to compare cardiovascular events between the two therapies in order to understand the mechanism behind the events."

Endologix's Chief Medical Officer, Matt Thompson, M.D., commented, "In earlier Nellix EVAS studies, all-cause and cardiovascular mortality were lower than expected, and this propensity-weighted analysis is the first contemporary comparison of the data. We are committed to the innovative aneurysm sealing approach and look forward to completing our EVAS2 confirmatory trial, which is required in support of FDA approval."

Since completion of the original 333-patient Nellix IDE trial, the Instructions for Use (IFU) have been refined to improve aneurysm-related outcomes. In March 2018, Endologix initiated the EVAS2 confirmatory IDE trial to evaluate the safety and effectiveness of the refined IFU together with the next generation Nellix EVAS System.

The data that serve as the basis for this analysis include patients under the original Nellix IFU criteria, and the analysis has not been reviewed by the FDA. The Nellix EndoVascular Aneurysm Sealing System is an investigational device in the U.S. and is limited by federal law to investigational use only. The Nellix EndoVascular Aneurysm Sealing System and associated components are not available in all countries or regions. In countries and regions in which it is approved, the Nellix EndoVascular Aneurysm Sealing System is approved to treat infrarenal abdominal aortic aneurysms and is not approved for any other intended use in any geography. Prior to use, refer to the IFU for complete and specific indications, contraindications, all warnings and precautions.

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 EVAS/EVAR comparison analysis and presentation of further results, continued development of EVAS therapy (and comparison as to EVAR), the potential of EVAS to improve patient outcomes, and conduct and completion of the EVAS2 confirmatory trial, 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 EVAS, and risks regarding conduct of the EVAS and EVAS2 clinical trials (and other EVAS trials and studies) and the results thereof. 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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