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Endologix Receives IDE Approval for the EVAS2 Confirmatory Clinical Study to Evaluate 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 it has received Investigational Device Exemption ("IDE") approval from the United States Food and Drug Administration ("FDA") to commence a confirmatory clinical study to evaluate the safety and effectiveness of the Nellix EndoVascular Aneurysm Sealing System ("EVAS") for the endovascular treatment of infrarenal abdominal aortic aneurysms. The EVAS2 IDE Multicenter Safety and Effectiveness Confirmatory Study ("EVAS2") will prospectively evaluate the refined Indications for Use (IFU) and the Nellix Gen2 EVAS System. The study is approved to enroll up to 90 primary patients, with one-year follow-up data required for the Pre-market Approval Application (PMA).

The Nellix EVAS 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.

John McDermott, Chief Executive Officer for Endologix, said, "We are pleased to receive IDE approval from the FDA to begin this confirmatory study and look forward to collaborating with the investigators to achieve the goal of commencing enrollment by the end of this year. Based on the anticipated enrollment timeline, one-year follow up period, and regulatory review process, we continue to estimate PMA approval in 2020."

About Endologix

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 U.S. For more information, visit www.endologix.com.

The Nellix® EndoVascular Aneurysm Sealing System has obtained CE Mark in the EU and is only approved as an investigational device in the United States.

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 confirmatory clinical study (including enrollment timeline), Endologix's ability to obtain regulatory approval of the Nellix EVAS System within currently anticipated timeframes, and future commercial availability of the Nellix EVAS 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, continued market acceptance, endorsement and use of Endologix's products (including market acceptance and adoption of the Nellix EVAS System with its refined IFU), risks associated with the manufacturing of Endologix's products, the success of clinical trials relating to Endologix's products (including the clinical results of the EVAS2 study), product research and development efforts, uncertainty in the process of obtaining and maintaining U.S. FDA and other regulatory approvals for Endologix's products, 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, 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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