Endologix Receives IDE Approval for the Nellix Chimney EndoVascular Aneurysm Sealing Protocol

August 8, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Aug. 8, 2019-- 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 new pivotal study to evaluate the safety and effectiveness of the Nellix Chimney EndoVascular Aneurysm Sealing System ("ChEVAS") for the endovascular treatment of complex abdominal aortic aneurysms ("AAA").

The ChEVAS system is an endovascular abdominal aortic aneurysm therapy designed to combine the Nellix 3.5 endograft with parallel visceral stents to enable treatment of patients with juxta-renal, para-renal, and suprarenal AAA. The application of endovascular aneurysm sealing ("EVAS") for patients with complex aneurysms will offer innovative new technology to a group of patients that are underserved by the current standard of care.

John Onopchenko, Chief Executive Officer for Endologix, commented, "We are pleased to receive IDE approval from the FDA to begin this study, which will recruit 120 patients with complex AAA in up to 50 centers, both in the USA and internationally. This approval marks another step forward on our path to re-establishing durable, predictable growth through a continued focus on execution and evidence-driven differentiation."

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. The Company's focus is in 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 an 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.

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: potential benefits of CHEVAS to patients; conduct of the CHEVAS IDE trial, and; Endologix's reestablishment of durable, predictable growth through a continued focus on execution and evidence-driven differentiation, 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, continued market acceptance, endorsement and use of Endologix's products, the success of clinical trials relating to Endologix's CHEVAS system and other products, timing and success of clinical trial enrollment and completion, product research and development efforts, uncertainty in the process of obtaining and maintaining regulatory approval for Endologix's products, Endologix's ability to continue to access the capital markets, Endologix's ability to protect its intellectual property rights and proprietary technologies, and other economic, business, competitive and regulatory factors. The forward-looking statements contained in this press release 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, 2018, and its 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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