



Endologix Announces Reinstatement of CE Mark for its Nellix EndoVascular Aneurysm Sealing System

June 6, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 6, 2019-- Endologix® Inc. (Nasdaq: ELGX), a developer and marketer of innovative treatments for aortic disorders, announced today that the EC Certificate of Conformity (CE Mark) for the Nellix EndoVascular Aneurysm Sealing System (Nellix System) has been reinstated by GMED, the EU Notified Body for the Nellix System. The reinstatement followed an assessment of clinical evidence.

"We continue to believe that the Nellix System has the potential to transform the treatment of patients with infra-renal abdominal aortic aneurysms," said Matt Thompson MD, Chief Medical Officer of Endologix, Inc. "This therapy continues to generate positive results when used in patients that conform to the anatomical indications for use. We are delighted that the available data supports the reinstatement of our CE mark, and we look forward to utilizing this technology to improve the patient experience and drive better outcomes."

As previously disclosed, the Nellix System will be made available for use at approved centers in a post-market clinical investigational setting outside the USA. Within the USA, the Nellix System remains an investigational device as part of the EVAS2 study.

The Company does not expect this reinstatement to impact its previously communicated financial guidance for 2019.

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: Endologix's plan to have the Nellix System be made available only for use at approved centers in a clinical investigation setting outside the United States; use of Nellix System to improve the patient experience and drive better outcomes; and Endologix's statement that it does not expect the reinstatement to impact previously communicated financial guidance for 2019, 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 Nellix System and other products, product research and development efforts, uncertainty in the process of obtaining and maintaining regulatory approval for Endologix's products including its CE Marking and similar regulatory clearances, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 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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Vaseem Mahboob
(949) 595-7200