



## **Endologix Takes Decisive Action to Optimize Patient Outcomes by Ensuring Nellix System Used Only within Current Indications**

January 4, 2019

*Voluntary Recall of Existing Inventory, New Cases Conducted Under Clinical Protocol, and Patient Selection Pre-Approved by Physician Panel*

*Decision Aligns with European Society for Vascular Surgery Practice Guidelines*

*No Change to Previously Issued Revenue Guidance for 2019*

*No Change to EVAS2 IDE*

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 4, 2019-- Endologix® Inc. (Nasdaq: ELGX) ("Endologix" or the "Company"), a developer and marketer of innovative treatments for aortic disorders, announced today that in order to ensure optimal outcomes for patients, unrestricted sales and use of the Nellix System will cease immediately, and the product will only be available for use under clinical protocol with pre-screened patients that adhere to the current indications.

"We monitor the performance of the Nellix System through clinical trials, our complaint monitoring system, physician interaction and available publications," said Dr. Matt Thompson, Chief Medical Officer of Endologix. "Our independently adjudicated data from the EVAS1 IDE clinical trial indicates that the Nellix System has performed well when used consistent with the current indications. However, data from recent Nellix publications leave us concerned that outcomes are suboptimal when the system is used outside current instructions for use."

To ensure optimal clinical outcomes, the Nellix System will, for the foreseeable future, only be available for use under clinical protocol with pre-screened patients that adhere to the current indications. All cases will be pre-screened by a physician panel and supported by Endologix clinical specialists to ensure adherence to protocol. Compassionate use requests will be reviewed in accordance with the process established by the Company and associated national competent authorities. The existing inventory will be voluntarily recalled. These actions are described in a Field Safety Notification (FSN) issued today.

"Ensuring patient safety and optimal clinical outcomes is our top priority, and the current level of off-label use of the Nellix System cannot continue if we are to protect and preserve the potential for transformative EndoVascular Aneurysm Sealing (EVAS) therapy," said John Onopchenko, Chief Executive Officer of Endologix. "Taking these actions aligns with clinical practice standards, allows us to control off-label use and will help us ensure appropriate application of the therapy."

This decision is one of several actions taken by Endologix following a new management mandate in August 2018 to ensure the most appropriate use of each of its devices and is in alignment with a recent publication by the European Society for Vascular Surgery (ESVS). Endologix has been in contact with regulatory authorities regarding the Nellix System recall and related matters to help ensure patient safety and continued appropriate access to the Nellix System.

Endologix refined the technical procedure of EVAS and voluntarily and proactively delivered clinical practice updates and advisories regarding use of the Nellix System through a series of FSNs developed in collaboration with regulatory authorities worldwide. Nevertheless, Endologix has determined that off-label use is occurring at an unacceptable level, with the consequence of sub-optimal results. The Company is taking action to ensure optimal outcomes for patients.

EVAS therapy was designed to overcome the durability issues of conventional EndoVascular Aneurysm Repair (EVAR) that have led to high rates of aneurysm related mortality when compared with surgical interventions. "When used as indicated, EVAS is associated with low rates of aneurysm sac growth, Type 2 endoleaks and all-cause mortality," said Mr. Onopchenko. "Our actions are intended to preserve and advance this therapy. Clinical data drives our decision making and is our basis for competing in the marketplace. Limiting the use of the Nellix System to only those cases rigorously adjudicated by a review board and performed under clinical protocol will ensure that high integrity data is generated and will enable us to deliver on the promise of this potentially disruptive therapy."

### **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](http://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 only for use under clinical protocol with pre-screened patients that adhere to the current indications; voluntary recall of existing Nellix inventory; intended pre-screening and case support process for future Nellix cases; compassionate use of the Nellix System; controlling off-label use and building data for on-label use; ensuring high integrity data regarding the Nellix System; and enabling Endologix to deliver on the promise of this*

*potentially disruptive EVAS therapy , 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, 2017, and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2018, June 30, 2018, and September 30, 2018 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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Source: Endologix® Inc.

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