Endologix Announces Reinstatement of CE Mark for AFX® and AFX2 Endovascular AAA Systems

IRVINE, Calif., Jan. 25, 2017 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, today announced that it received notice from its Notified Body in the European Union that the CE Mark for the AFX® and AFX2 Endovascular AAA Systems has been reinstated, effective immediately.

John McDermott, Chief Executive Officer of Endologix, said, “We are pleased that AFX and AFX2 are once again available to physicians and patients in Europe. The quick reinstatement of the CE Mark is a testament to the strong commercial clinical results achieved with the current generations of the device. Additionally, during this process we received numerous letters and endorsements from physicians worldwide and we’d like to thank them for their support.”

The CE Mark was temporarily suspended due to reports of Type III endoleaks with a prior generation of the AFX system. The CE Mark was reinstated based upon low rates of reported Type III endoleaks with the current generation of AFX products, which was also outlined in a recent letter to physicians provided by Endologix.

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. Additional information can be found on Endologix's website at www.endologix.com.

Forward-Looking Statements

This communication includes statements that may be "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to availability for sale of AFX devices in the EU, the accuracy of which are necessarily subject to risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Endologix. Many factors may cause actual results to differ materially from anticipated results, unexpected delays in process and testing improvements and additional regulatory requirements. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Endologix undertakes no obligation to update any forward-looking statements 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 Annual Report on Form 10-K for the year ended December 31, 2015, and Endologix's subsequent filings with the Securities and Exchange Commission, for more detailed information regarding these risks and other factors that may cause actual results to differ materially from those expressed or implied.

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