Endologix Provides Update on Nellix PMA Process

IRVINE, Calif., Nov. 16, 2016 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that the U.S Food and Drug Administration (FDA) has requested the Company provide 2-year patient follow-up data from the EVAS-FORWARD IDE Study of the Nellix® EndoVascular Aneurysm Sealing System (Nellix EVAS System). The Company expects these data to be available and submitted to the FDA in the second quarter of 2017, followed by a possible FDA advisory panel meeting by the end of 2017, and potential FDA PMA approval of Nellix in the second quarter of 2018.

John McDermott, Chief Executive Officer of Endologix, said, "We're disappointed by these requirements and the resulting delay, but encouraged by the 2-year clinical outcomes we have seen so far with Nellix under our newly revised instructions for use. We remain committed to EVAS with Nellix and have demonstrated outstanding clinical results in selected patients with both traditional and complex AAA anatomies. We look forward to providing this important new technology to physicians and patients in the U.S. and other markets as soon as possible."

Nellix is an investigational device in the United States.

The company will discuss the updated Nellix PMA process as part of its business overview at its 2016 Investor Meeting, which is scheduled for Thursday, November 17, 2016. The Investor Meeting will be held on November 17, 2016 from 4:30 to 7:00 pm ET at the Sheraton New York Times Square Hotel in New York City. The event will include a Company update along with presentations from prominent physicians on the Company's product portfolio and a question and answer session with the physicians and Endologix management.

Event: Endologix Investor Meeting
Date: November 17, 2016
Time: 4:30 to 7:00 pm ET (registration and refreshments begin at 4:30 pm ET; formal presentation begins at 5:00 pm ET)
Location: Sheraton New York Times Square Hotel
811 7th Ave 53rd Street, New York, NY

A live audio webcast of the investor meeting will be available by visiting the investor relations section of Endologix's website at www.endologix.com. Participants are encouraged to log on a few minutes prior to 5:00 pm ET in order to download any applicable audio software. A replay of the presentation will be available within 24 hours and will be available for approximately one year.

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 clinical outcomes and regulatory approval timelines, 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, including unanticipated clinical outcomes 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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Source: Endologix
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