Endologix Provides an Update on the Nellix® Endovascular Aneurysm Sealing System

U.S. Regulatory Status

Company to Host an Investor Conference Call on May 18, 2017 at 7:30 a.m. ET

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix, Inc. (Nasdaq:ELGX), a developer and marketer of innovative treatments for aortic disorders, today announced that the Company met with the Food and Drug Administration (FDA) regarding its Nellix® Endovascular Aneurysm Sealing System (the Nellix® EVAS System).

Based upon that meeting and further internal analysis, the Company has determined that it will seek U.S. approval of the Nellix® EVAS System by conducting a confirmatory clinical study with the previously updated Instructions for Use (IFU) and the Gen2 device design, which is currently sold in Europe and other international markets. The Company will collaborate with the FDA over the coming months on the confirmatory clinical study protocol and anticipates beginning patient enrollment in the fourth quarter of this year with PMA approval estimated to occur in 2020.

John McDermott, Chief Executive Officer of Endologix, Inc., commented, "While the timeline has shifted from our projections, we appreciate the FDA's collaboration as Nellix® EVAS proceeds in the regulatory process. We have evidence that our previously updated Nellix® IFU provides excellent patient outcomes and look forward to starting the confirmatory clinical study with our Gen2 device. We appreciate the support of our physicians worldwide and their continued collaboration in developing new technologies and conducting clinical studies to provide the best outcomes for patients with abdominal aortic aneurysms."

Positive clinical outcomes with the Nellix® EVAS System will be reported at upcoming medical meetings, including Critical Issues in Aortic Endografting in Nuremburg, Germany on May 19 and May 20, 2017 and the 2017 Vascular Annual Meeting in San Diego, California on May 31 through June 3.

Conference Calls

The Company will host a conference call at 7:30 a.m. ET on May 18, 2017 to discuss the information contained in this press release. To participate in the conference call, dial 888-576-4382 (domestic) or 719-325-2190 (international). The conference call will also be webcast and can be accessed from the "Investors" section of the Company's website at www.endologix.com. The webcast replay of the call will be available at the same site approximately one hour after the end of the call.

Additionally, the Company will host a previously announced conference call at 3:00 p.m. ET on June 3, 2017 to discuss Dr. Jeffrey Carpenter's presentation of "Refinement of the IFU for the Nellix® System for Endovascular Aneurysm Sealing Based Upon Outcomes From the EVAS FORWARD IDE Trial" at the Society of Vascular Surgery ("SVS").

Supplemental Slides

Supplemental slides will be available by 7:00 a.m. ET on May 18, 2017 on the "Investors - Events & Presentations" section of the Company's website at www.endologix.com.

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. For more information, visit 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 enrollment in clinical trials, clinical outcomes with the new IFU and Nellix® Gen2 device, and the timeline for regulatory actions, 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, the timing and results of clinical trials, uncertainties in regulatory actions and timing, 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, 2016, 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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