Endologix Receives FDA Approval for Alto Abdominal Stent Graft System

March 16, 2020

IRVINE, Calif.--(BUSINESS WIRE)-- Endologix® Inc. (Nasdaq: ELGX) (“Endologix” or the “Company”), a developer and marketer of innovative treatments for aortic disorders, today announced that it has received approval from the United States Food and Drug Administration (FDA) for the Alto™ Abdominal Stent Graft System (Alto).

The Company received approval based on its regulatory submission that includes the ELEVATE Investigational Device Exemption (IDE) clinical study. Pursuant to the terms of approval, the first 100 patients after commercial launch will be included in a post approval imaging study to determine consistency in device selection between Endologix’s internal imaging services and those of the implanting physicians.

“We are thrilled to receive approval for the Alto system,” commented Matt Thompson, Chief Medical Officer of Endologix. “We have worked collaboratively with the FDA throughout the Alto premarket approval (PMA) process, and we will be carefully monitoring intra-procedural events as Alto ramps to full commercialization. We anticipate observing improved short-term outcomes relative to the Ovation iX Abdominal Stent Graft System (Ovation iX) as a result of the design and manufacturing changes incorporated into Alto. However, as we expect Ovation iX to remain commercially available for a period of time subsequent to the Alto launch, we will also be updating our previous 2018 safety communication as it relates to the Ovation iX system.”

“Alto approval is a critical landmark for Endologix as we seek to introduce a portfolio of devices to address the current unmet needs of endovascular aneurysm repair (EVAR),” commented John Onopchenko, Chief Executive Officer of Endologix. “Alto is a differentiated EVAR device that offers significant design features that we believe will enhance ease of use, improve acute outcomes, and preserve the long-term durability associated with patient-specific anatomically adaptive sealing. We believe Alto’s ultra-low profile and its 7mm aortic neck length indication give it the broadest applicability of any endograft in the U.S. We are committed to proving the superiority of this product over traditional undifferentiated EVAR grafts in a randomized clinical trial, while remaining steadfastly focused on re-establishing durable, predictable growth through a continued focus on execution and evidence-driven differentiation.”

About Endologix, Inc.

Endologix 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 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 statements regarding: Endologix’s performance of a 100-patient imaging study per the terms of FDA’s approval; monitoring of intra-procedural events; anticipated observation of improved short-term outcomes for Alto as relative to the Ovation iX system; anticipated updates to Endologix’s previous 2018 safety communication as it relates to the Ovation iX system; perceived benefits of Endologix’s Alto product; Endologix’s intent to prove the superiority of Alto over traditional undifferentiated EVAR grafts in a randomized clinical trial; and Endologix’s ability to re-establish durable, predictable growth, the accuracy of each 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 Alto system and other products, timing and success of clinical trial enrollment and completion, product research and development efforts, uncertainty in the process of obtaining and maintaining regulatory approval for Endologix's products, Endologix’s ability to comply with and discharge its obligations under its debt agreements with its secured lenders, Endologix’s ability to continue to access the capital markets and to otherwise procure capital necessary to fund its business as needed, 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. Although we believe that the forward-looking statements contained herein are reasonable, we can give no assurance that our expectations are correct.

All forward-looking statements are expressly qualified in their entirety by this cautionary statement. 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, 2019, and its subsequent Quarterly Reports on Form 10-Q 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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