



Endologix Announces Completion of Enrollment in the EVAS2 Confirmatory Clinical Study to Evaluate the Nellix EndoVascular Aneurysm Sealing System

May 11, 2020

IRVINE, Calif.--(BUSINESS WIRE)--May 11, 2020-- Endologix® Inc. (Nasdaq: ELGX) ("Endologix" or the "Company"), a developer and marketer of innovative treatments for aortic disorders, today announced that it has completed enrollment in the EVAS2 Confirmatory Clinical Study to Evaluate the Nellix EndoVascular Aneurysm Sealing (EVAS) System.

"The completion of enrollment in our EVAS2 study is an exciting milestone for Endologix and for the treatment of abdominal aortic aneurysms," commented John Onopchenko, Chief Executive Officer of Endologix. "We are very grateful for the ongoing collaboration and partnership with our investigators who continue to work side-by-side with us to make this trial successful."

In response to the current COVID-19 pandemic and the delay in recruiting patients across many clinical trials, Endologix submitted an IDE supplement to the FDA with a revised Statistical Analysis Plan that is consistent with the recently published FDA Guidance document, *Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic*.

The submission proposed a minimum sample size of 95 patients, with no alteration to the defined end points of the study. The power of the two-year effectiveness endpoint has been reduced to 87.4% from 93.8%, and the power of the safety endpoint remains 99.9%. The statistical power of both end points remains well above the 80% benchmark typically used in this therapeutic area.

The Company is currently in the process of preparing a PMA submission, which it plans to submit shortly after the first 95 patients in the trial reach one-year follow-up in March 2021.

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: the ability of Endologix's EVAS system to successfully treat abdominal aortic aneurysms, the continued collaboration of Endologix's investigators, the preparation and timing of submission of Endologix's PMA, 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200511005775/en/): <https://www.businesswire.com/news/home/20200511005775/en/>

INVESTOR CONTACT:
Endologix, Inc.
Vaseem Mahboob, CFO
(949) 595-7200

Source: Endologix, Inc.