April 16, 2013

Endologix Announces FDA Approval of First Percutaneous Indication for Endovascular Abdominal Aortic Aneurysm Repair

IRVINE, Calif., April 16, 2013 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that it has received U.S. Food and Drug Administration (FDA) approval of its premarket approval (PMA) supplement for a broadened indication for the Company's 21Fr profile and smaller EVAR systems to include totally percutaneous endovascular aneurysm repair (PEVAR) based upon the outcomes of the first prospective, multicenter, randomized clinical trial (The PEVAR Trial). The Endologix EVAR platforms include the Powerlink® with IntuiTrak® System and the AFX™ Endovascular AAA System, which are the first and only among commercially available endografts to achieve the totally percutaneous labeling expansion facilitated using the Perclose ProGlide® Suture-Mediated Closure System made by healthcare company Abbott. The Company expects to begin training physicians in the U.S. on the PEVAR procedure in the second quarter 2013.

The FDA approval provides the first clinical validation of PEVAR in a multicenter setting using the Company's fully integrated, sheath-based EVAR systems that already had the industry's only contralateral standard percutaneous (9Fr) indication. The trial results, presented at recent medical meetings, found significant benefits following PEVAR compared to surgical vascular access EVAR. PEVAR procedures were completed in 34 minutes less time, required eight times fewer concomitant iliac/femoral artery procedures or repairs, and resulted in achievement of femoral artery hemostasis in 57% less time. Other positive trends favoring PEVAR included reduced blood loss with 72% fewer patients requiring a blood transfusion, 2.5 times fewer patients with a serious adverse event, nearly 50% fewer patients needing analgesics or narcotics for groin pain, and discharge from the hospital 0.5 days earlier.

John McDermott, Chairman, President and Chief Executive Officer of Endologix, said, "We are pleased to receive FDA approval for our PEVAR indication, which provides our sales force with another unique AAA technology to offer our customers. We are now the first and only Company to receive a percutaneous indication for EVAR, which will allow us to begin training physicians on the PEVAR procedure using our unique platform of EVAR systems. We believe physicians and hospitals will be attracted to PEVAR because it is a less invasive procedure that has the potential to significantly reduce procedure times and improve the patient experience. We expect to begin PEVAR training courses in the second quarter, which will lead to a gradual increase in the number of percutaneous cases performed as we progress through the year."

About Endologix, Inc.

Endologix, Inc. develops and manufactures minimally invasive treatments for aortic disorders. Endologix 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 75%, making it a leading cause of death in the U.S. Additional information can be found on Endologix's website at www.endologix.com.

Forward Looking Statements

Except for historical information contained herein, this news release contains forward-looking statements with respect to training on the PEVAR procedure, the utilization of the PEVAR procedure and increase in percutaneous cases, the accuracy of which are necessarily subject to risks and uncertainties, which are difficult or impossible to predict accurately and some of which are beyond the control of Endologix. Many factors may cause actual results to differ materially from anticipated results, including uncertainties in the acceptance of PEVAR procedures by physicians and payers. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. The Company 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2012, and the Company's other 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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