Endologix Announces Presentation of Data From PEVAR Randomized Trial

94% Procedural Technical Success Rate; Significantly Reduced Procedure Times and Time to Hemostasis

IRVINE, Calif., Jan. 28, 2013 (GLOBE NEWSWIRE) -- Endologix, Inc. (Nasdaq:ELGX), developer and marketer of innovative treatments for aortic disorders, announced today that data from the first prospective, multicenter, randomized clinical trial of a totally percutaneous approach (PEVAR) to endovascular abdominal aortic aneurysm repair (EVAR) was recently presented at two medical meetings. The presentation on the closure device independent substudy was made by Zvonimir Krajcer, MD (Program Director - Peripheral Vascular Interventions, Department of Cardiology, St. Luke's Episcopal Hospital at the Texas Heart Institute, Houston, TX) at the 25th Annual International Symposium on Endovascular Therapy (ISET), which took place January 19-23, 2013. The presentation on the PEVAR Trial primary analysis was made by Peter R. Nelson, MD, MS (Assistant Professor of Vascular Surgery at University of Florida, Gainesville, FL) at the 37th Annual Meeting of the Southern Association for Vascular Surgery (SAVS), which took place January 23-26, 2013.

The presentations by Dr. Krajcer and Dr. Nelson reported the randomized trial results comparing PEVAR using the Endologix 21Fr (OD) sheath based system delivered using a percutaneous approach (the 'pre-close' technique) using the Perclose ProGlide® Suture-Mediated Closure System¹, made by healthcare company Abbott, with surgical access EVAR. Key points from the trial include:

- The primary trial endpoint was met (P < .0036), definitively demonstrating the non-inferiority of PEVAR using the ProGlide closure device to surgical EVAR
- A 94% procedural technical success rate was achieved in a multicenter setting
- Mean procedure time was reduced in PEVAR patients by 34 minutes (P=.006). Likewise, mean time to hemostasis was reduced following PEVAR by 13 minutes (P=.002)
- PEVAR patients required significantly fewer concomitant procedures
- Favorable trending of PEVAR in several clinical utility outcomes including reduced anesthesia time, reduced blood loss and need for transfusion, shorter hospital length of stay, and less analgesics prescribed for groin pain
- The PEVAR non-inferiority to surgical EVAR persisted through the final 6-month follow-up

The PEVAR Trial was designed to support the safety and effectiveness of the Company’s 21Fr and smaller profile EVAR platforms, including the Powerlink® with IntuiTrak System and the AFX™ Endovascular AAA System in the percutaneous treatment of abdominal aortic aneurysm. The Company anticipates the full data from the presentation made by Dr. Nelson will be published in the Journal of Vascular Surgery during the second quarter 2013.

John McDermott, Chairman, President and Chief Executive Officer of Endologix, said, "The positive results from our PEVAR Trial provide strong clinical evidence supporting a totally percutaneous approach using our integrated sheath-based systems in EVAR procedures. The study demonstrated that PEVAR is non-inferior to surgical EVAR, with significantly reduced procedure times and time to hemostasis. The study also showed positive trends towards lower blood loss, less need for pain medication, and shorter lengths of stay, which are attractive for physicians, hospitals and patients. There was strong interest in the PEVAR data at ISET and SAVS meetings and we remain well positioned, pending FDA approval, to begin training physicians on the PEVAR procedure."

About ISET

Begun in 1989 and led by acclaimed interventionist Barry Katzen, M.D., ISET is attended annually by physicians, scientists, allied health professionals and industry professionals from around the world. The meeting pioneered the use of live case demonstrations as an educational tool and promotes the interdisciplinary treatment of cardiac and vascular disease by endovascular means.

About SAVS

The Southern Association for Vascular Surgery is a vascular surgical organization established to promote the art and science of peripheral vascular surgery, to further education, and to perpetuate friendships of its members. It is comprised of over 500 active, senior, candidate, honorary and corresponding members primarily from the 13 southern
states of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Washington DC.

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.

1 CAUTION: This press release discusses the use of the Perclose ProGlide in an investigational manner, as being used in an FDA-approved IDE trial. The product is limited by Federal (or United States) law to investigational use. Not approved or available for sale for expanded indications.

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