Endologix Announces 12-Month Results of DETOUR-2 Trial at 2022 VIVA Late-Breaking Clinical Trial Session

**IRVINE, Calif. November 10, 2022—**[Endologix LLC](https://endologix.com/), a privately held global medical device company dedicated to improving patients’ lives by providing disruptive therapies for the interventional treatment of vascular disease, announced the 12-month results of the DETOUR 2 trial during a late-breaking clinical trial sessions at the 2022 VIVA Vascular InterVentional Advances (VIVA) Conference in Las Vegas, Nevada.

DETOUR 2 is an Investigational Device Exemption (IDE) study, designed to evaluate safety and effectiveness of the DETOUR System for percutaneous bypass in the treatment of long-segment femoropopliteal disease. The primary safety endpoint is a composite outcome of major adverse events (MAE) through 30 days, and consists of death, CD-TLR, amputation of the target limb, symptomatic deep vein thrombosis (DVT), pulmonary embolism (PE), and the need for transfusion of packed red blood cells (PBRC) at the index procedure.

The DETOUR 2 clinical trial has enrolled 202 patients in the United States and Europe for the primary analyses. A Pre-Market Approval (PMA) Application for the DETOUR Systems was submitted to the FDA in October 2022. The 12-month results from the study were presented at 2022 VIVA Conference by one of the study’s principal investigators, Dr. Sean Lyden, Chairman of the Department of Vascular Surgery at Cleveland Clinic’s Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute. The results presented are listed below:

* + Ninety-six percent of enrolled patients had chronic total occlusions, with a mean lesion length of 32.7cm.
  + Technical success was achieved in 100% of treated patients and the primary safety endpoint was surpassed with a 30-day MAE rate of 7.0%.
  + The 1-year effectiveness endpoint was also met, with 72.1% freedom from CD-TLR and recurrent stenosis > 50% at 12 months. The primary assisted patency was 77.7% at 12 months. The secondary patency at 12 months was 89%.
  + There was marked improvement in Quality of Life as measured by the EQ-5D-5L index when comparing pre- and post-treatment scores. Mean index values of 0.69, 0.77, and 0.80, were seen at baseline, 30 days, and 12 months respectively. Mean EQ VAS scores were 62.8, 72.1, and 70.5 over the same periods.

“This system has potential to introduce a minimally invasive alternative for patients in need of a femoropopliteal bypass. The low MAE rate, coupled with good primary patency provides supportive data for the feasibility of this new technology in a challenging patient population,” said Dr. Lyden.

“DETOUR 2 showed promising results in both safety and efficacy among patients treated with endovascular approach for long complex SFA/POP occlusions including severe calcification, in stent restenosis, and long occlusions. The recently presented data are extremely encouraging. In many patients who may not be candidates for surgical or native endovascular revascularizations, the DETOUR procedure will provide them with a new treatment modality,” said Jihad Mustapha MD, FACC, FSCAI, co-principal investigator for the DETOUR 2 trial, President and Chief Executive Officer and Director of Endovascular Interventions at Advanced Cardiac & Vascular Centers for Amputation Prevention.

“We are delighted to present results of the first-ever, fully percutaneous, transmural arterial bypass (PTAB) therapy. PTAB is performed using the DETOUR System, which earned FDA Breakthrough Device Designation, and is comprised of the ENDOCROSS™ Device and TORUS™ Stent Graft,” said Matt Thompson, President and CEO of Endologix. “The presentation of this study represents an important milestone in our effort to bring this novel therapy to market, as we seek U.S. regulatory approval to offer endovascular alternatives to open lower limb bypass for patients with long femoropopliteal occlusions.”

**About Endologix**

Endologix LLC is a California-based, global medical device company dedicated to improving patients’ lives by providing innovative therapies for the interventional treatment of vascular disease. Endologix’s therapeutic portfolio includes a variety of products in various stages of development that are designed to treat diseases that currently have clinically relevant unmet needs. These products are designed to treat a wide spectrum of vascular disease from abdominal aortic aneurysms to lower limb peripheral vascular disease. Endologix’s current commercial EVAR products include the AFX®2 Endovascular AAA System and the ALTO® Abdominal Stent Graft System. On October 1, 2020, Endologix became a private company, wholly owned by Deerfield Management, an investment management firm committed to advancing healthcare through investment, information, and philanthropy. In April 2021, Endologix completed the acquisition of PQ Bypass, Inc., a privately held medical technology, adding the DETOUR System and TORUS Stent Graft to the Company’s product pipeline. The DETOUR System and the TORUS Stent Graft have not been approved for sale by any regulatory body. The DETOUR System is an investigational device, limited by United States law to investigational use.

The company has offices and manufacturing sites in Irvine and Santa Rosa, California. To learn more about Endologix, please visit <https://www.endologix.com/>.

Except for historical information contained herein, this press release contains forward-looking statements, including statements regarding the ability to obtain U.S. regulatory approval for our DETOUR System under development, the subsequent indications for use and commercial availability of the DETOUR System. Forward-looking statements are subject to risks and uncertainties and other factors that may cause actual results to differ materially from those expressed or implied. The forward-looking statements contained in this press release speak only as of the date of this press release and 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.

**Contacts**

Endologix LLC  
Sandy Prietto  
949-595-7240  
sprietto@endologix.com