Surmodics Announces First Patient Enrolled in TRANSCEND Pivotal Clinical Trial for SurVeil® Drug-Coated Balloon

October 23, 2017

Comparing SurVeil® DCB to Medtronic IN.PACT® Admiral® DCB

Plan to enroll up to 446 patients at approximately 78 sites

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 23, 2017-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced enrollment of the first patient in TRANSCEND, the pivotal clinical trial for the SurVeil® drug-coated balloon (DCB). The randomized trial will evaluate the *SurVeil* DCB for treatment for peripheral artery disease (PAD) in the upper leg compared to a commercially available DCB treatment. Up to 446 patients will be randomized 1:1 to receive either the *SurVeil* DCB or Medtronic's IN.PACT® Admiral® DCB at approximately 60 U.S. sites and 18 sites outside the United States.

"Based on the preclinical and early feasibility study results we have seen so far, I am excited about the potential of the *Surveil* DCB as a third-generation DCB to improve the treatment of PAD," said Kenneth Rosenfield, M.D., section head, Vascular Medicine and Intervention at Massachusetts General Hospital, chair of the Surmodics Clinical Advisory Board and U.S. co-principal investigator for the TRANSCEND trial. "TRANSCEND will be a rigorous Level One trial that will answer important questions about DCB technologies."

The design of the *Surveil* DCB reflects Surmodics' long-standing industry leadership in the development of surface technology for vascular medical devices. The device includes a proprietary drug-excipient formulation for the balloon coating and is manufactured using a proprietary process to improve coating uniformity. Pre-clinical data have shown a three to five times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug particles compared to control DCBs.[1]

"This is a major step in the right direction for Surmodics, as we apply and evaluate our unique technology with the goal of improving clinical outcomes for patients with peripheral artery disease," said Gary Maharaj, president and CEO of Surmodics. "We're thrilled to be underway with TRANSCEND and look forward to working with our investigators to execute an efficient and rigorous pivotal trial."

About the TRANSCEND Pivotal Trial

The objective of the *Surveil* DCB pivotal trial, TRANSCEND, is to evaluate the safety and effectiveness of the device for treatment of subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. The clinical study will be used to support regulatory approvals (U.S. and Europe) and reimbursement. The primary efficacy endpoint of the trial is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization (TLR) through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure.

The trial will be led by national co-principal investigators Kenneth Rosenfield, M.D., and Gary Ansel, M.D., system medical chief of the Vascular Program at OhioHealth. Marianne Brodmann, M.D., substitute head of the Division of Angiology, Department of Internal Medicine, Medical University of Graz, Graz, Austria, is the European principal investigator.

The *Surveil* DCB is not available for sale anywhere in the world, and is for investigational use only.

About Peripheral Artery Disease

Worldwide, over 200 million people have PAD,[2] a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Twelve to 20 percent of Americans over 60 years old have PAD.[3] PAD increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.[4]

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total solutions, Surmodics' mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the company, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding the impact and success of the clinical evaluation of the *Surveil* DCB, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) our ability to successfully, and in a timely fashion, develop, obtain regulatory approval for, and commercialize our *Surveil* DCB, and other proprietary products; (2) our ability to achieve expected benefits from our acquisitions; (3) possible adverse market conditions and possible adverse impacts on our cash flows, and (4) the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year

ended September 30, 2016, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at www.surmodics.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

[1]Surmodics data on file

[2] Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.

[3]Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.

[4]National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

View source version on businesswire.com: http://www.businesswire.com/news/home/20171023005341/en/

Source: Surmodics, Inc.

Surmodics, Inc.
Andy LaFrence, 952-500-7000
ir@surmodics.com