Surmodics Announces TRANSCEND Trial 24-Month Data to be Presented at VIVA 2022

October 26, 2022

Dr. Kenneth Rosenfield to share study results during Nov. 1 late-breaking trial session

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 26, 2022-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 24-month data from its TRANSCEND clinical trial will be presented at the upcoming Vascular InterVentional Advances (VIVA) annual conference in Las Vegas.

Dr. Kenneth Rosenfield, a principal investigator of the TRANSCEND study, will present the TRANSCEND trial's safety and efficacy data as part of a November 1 late-breaking clinical trials session. Preliminary schedule details are provided below:

TITLE:	Intermediate Term (24-Month) Results of the TRANSCEND Study Comparing a Next-Generation Paclitaxel Drug-Coated Balloon (SurVeil™ DCB) to IN.PACT® Admiral® DCB in the Treatment of Femoropopliteal Artery Disease**.**
SPEAKER:	Dr. Kenneth Rosenfield
SESSION:	Late Breaking Clinical Trials
DATE/TIME:	Tuesday, November 1, 2022
	Session – 10:45 a.m. to 12:00 p.m. (PDT)
	Presentation – 10:45 a.m. to 10:55 a.m. (PDT)

About the TRANSCEND Clinical Trial

The TRANSCEND trial randomized 446 patients at 65 global sites to assess the safety and efficacy of the SurVeil drug coated balloon (DCB) versus the IN.PACT® Admiral® DCB for treatment of superficial femoral and proximal popliteal artery lesions. The primary efficacy endpoint is 12-month primary patency, defined as freedom from binary restenosis or clinically driven target lesion revascularization (CD-TLR). The primary safety endpoint is freedom from device or procedure related death within 30 days and above-ankle amputation or CD-TVR within 12 months. Non-inferiority is tested using a multiple imputation approach at one-sided alpha 0.025.

Results at 12 months, presented by Dr. Rosenfield at the Leipzig Interventional Course (LINC) in 2021, demonstrated that the SurVeil DCB is non-inferior to the IN.PACT Admiral DCB with regards to both safety and efficacy, while delivering a substantially lower drug dose. Both the SurVeil and IN.PACT Admiral DCBs utilize coatings with the anti-proliferative drug paclitaxel. However, the IN.PACT Admiral DCB has a 75% higher drug load of paclitaxel (3.5 µg/mm^2) than the SurVeil DCB, which has a 2.0 µg/mm² drug load.

About the SurVeil DCB

The SurVeil DCB, a next-generation device that utilizes best-in-class technology in the treatment of peripheral artery disease (PAD), includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. In February 2018, Surmodics entered into an agreement with Abbott (NYSE: ABT) that provided Abbott with exclusive worldwide commercialization rights for the SurVeil DCB. Upon U.S. regulatory approval of the device, Surmodics will be responsible for manufacturing clinical and commercial quantities of the product and will realize revenue from product sales to Abbott as well as a share of profits resulting from sales to third parties. The SurVeil DCB received CE Mark Certification in the European Union in June 2020. In the United States, the SurVeil DCB is an investigational device, limited by Federal law to investigational use.

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) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, 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 the anticipated presentation on the TRANSCEND clinical trial, the potential clinical uses of the SurVeil DCB, Surmodics' potential responsibilities and revenues upon

U.S. regulatory approval of the device, and the company's growth strategy, 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 changes to the schedule of the VIVA 2022 Conference, failure of the U.S. Food and Drug Administration to grant premarket approval for the SurVeil DCB, and 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, 2021, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at https://surmodics.gcs-web.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.

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