12-Month Data from Surmodics' TRANSCEND Trial Presented at LINC 2021 Event

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SurVeil™ Drug Coated Balloon (DCB) demonstrates non-inferior safety and efficacy, while using a substantially lower drug dose, vs. the IN.PACT® Admiral® DCB for treatment of femoropopliteal lesions.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jan. 25, 2021-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 12-month data from its TRANSCEND clinical trial has been presented at the Leipzig Interventional Course (LINC) 2021 virtual event.

The TRANSCEND Trial is a global, multi-center, randomized, controlled clinical trial (RCT) with 1:1 randomization to the SurVeil™ DCB (Surmodics, Inc.) or IN.PACT® Admiral® DCB (Medtronic), in patients with symptomatic femoropopliteal artery disease. The primary efficacy endpoint was primary patency at 12 months, defined as a composite of freedom from clinically driven target lesion revascularization (CD-TLR) and binary restenosis. The primary safety endpoint was a composite of freedom from device or procedure related death through 30 days and freedom from above-ankle amputation and clinically driven target vessel revascularization (CD-TVR) within 12 months.

Primary results, presented by TRANSCEND co-principal investigator Dr. Kenneth Rosenfield, M.D., demonstrate 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.

"The TRANSCEND clinical trial is the first head-to-head pivotal RCT of a low-dose DCB (the SurVeil device) vs high-dose DCB (the IN.PACT Admiral device). The SurVeil DCB is a third-generation device that uses a substantially lower drug dose with an innovative drug-excipient formulation and process to achieve comparable clinical results. The drug coating is visibly different from other DCBs and is designed to improve drug consistency and uniformity while reducing particulate and downstream embolization, which are critical considerations in this patient population," said Dr. Rosenfield. "I am very pleased with the results presented today and excited about the potential of the SurVeil DCB, which offers an attractive therapeutic alternative to improve the treatment of PAD."

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/mm2) than the SurVeil DCB, which has a 2.0 µg/mm² drug load.

In the TRANSCEND Trial, the SurVeil DCB was found to be non-inferior to the IN.PACT Admiral DCB in both the primary safety and primary efficacy endpoints. The SurVeil DCB cohort (N=222) exhibited a strong safety profile with 91.7% of subjects demonstrating freedom from device or procedure related death within 30 days and freedom from above-ankle amputation or CD-TVR within 12 months, compared to 89.6% of subjects treated with the IN.PACT Admiral DCB (N=224). The SurVeil DCB group, also met its efficacy endpoint of primary patency of 81.7% as compared to 85.9% of the IN.PACT Admiral DCB arm. In addition, the number of reinterventions deemed clinically necessary by physicians did not differ between the products.

"We are grateful to Dr. Rosenfield, co-principal investigators Marianne Brodmann, M.D. and William Gray, M.D, and all the physicians and coordinators for their commitment to this important first of its kind clinical trial during a worldwide pandemic," said Gary Maharaj, president and chief executive officer of Surmodics. "TRANSCEND demonstrates that achieving clinically safe and effective outcomes with a substantially lower dose of Paclitaxel is achievable with the SurVeil DCB, which sets a new standard with its proprietary coating technology and therapeutic choice for physicians and the patients that they treat."

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 the 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.

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. The design of the SurVeil drug-coated balloon reflects Surmodics' industry leadership in the development of surface technology for vascular medical devices. The SurVeil DCB is not available for sale and is for investigational use only in the United States.

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 potential clinical uses of the SurVeil DCB, the consequences to Surmodics of regulatory approval of the SurVeil DCB, 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 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, 2020, 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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