Surmodics Announces TRANSCEND Trial 36-Month Data Presented at 50th Annual VEITH Symposium

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EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 16, 2023-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 36-month data from its TRANSCEND clinical trial was presented by Dr. Peter A. Schneider at the 50th Annual VEITH Symposium in New York, New York.

The TRANSCEND trial is a prospective, multi-center, single-blind, randomized, controlled trial 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. A total of 446 patients were randomized to either the low-dose paclitaxel (2.0 µg/mm2) SurVeil DCB (n = 222) or the high-dose (3.5 µg/mm2) paclitaxel IN.PACT Admiral DCB (n = 224) at 65 sites in the United States, Australia, Austria, Belgium, Czech Republic, Germany, Italy, Latvia and New Zealand.

The primary efficacy endpoint is 12-month primary patency, defined as freedom from binary restenosis or clinically driven target lesion revascularization (CD-TLR). Primary patency was comparable between the SurVeil DCB and IN.PACT Admiral (82.2% vs 85.9%). 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, which also demonstrated comparable outcomes between SurVeil DCB and IN.PACT Admiral DCB (91.8% vs 89.9%). Non-inferiority was tested using a multiple imputation approach at one-sided alpha 0.025.

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

Patient outcomes are being collected at 1, 6, 12, 24, 36, 48, and 60 months. Intermediate-term (36-month) secondary outcomes included clinically driven target lesion revascularization (CD-TLR), major target limb amputation (TLA), thrombosis at the target lesion, and historical major adverse events.

A total of 352/363 (96.97%) patients completed their 36-month visit.

The SurVeil DCB, which previously demonstrated noninferior primary safety and effectiveness outcomes through 12 months with a lower paclitaxel dose, continues to demonstrate similar outcomes at intermediate-term follow-up of 36 months compared with the high-dose IN.PACT Admiral DCB in the treatment of patients with symptomatic peripheral artery disease (PAD) caused by stenosis of the femoral and/or popliteal arteries. Results at 36 months for SurVeil versus IN.PACT Admiral were statistically comparable, including CD-TLR (20.3% vs 19.5%; *P* =0.897), major TLA (0.0% vs 0.5%; *P* = 1.000), thrombosis at the target lesion (0.6% vs 0.0%; *P* = .475), and historical MAEs (28.6% vs 28.5%; *P* = 1.000).

"The TRANSCEND 36-Month data continues to demonstrate safe and effective performance of the SurVeil DCB. SurVeil DCB is a best-in-class, high-quality treatment option for our PAD patients utilizing a next generation surface coating with a lower dose of Paclitaxel compared to IN.PACT Admiral DCB," said Dr. Peter A. Schneider.

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 SurVeil DCB received CE Mark Certification in the European Union in June 2020 and received FDA approval in the United States in June 2023.

In February 2018, Surmodics entered into an agreement with Abbott (NYSE: ABT) that provided Abbott with exclusive worldwide commercialization rights for the SurVeil DCB. With U.S. regulatory approval of the device, Surmodics will retain responsibility for manufacturing 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.

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 future collection of data in the TRANSCEND clinical trial, the potential clinical uses of the SurVeil DCB, Surmodics' potential responsibilities and revenues, 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, 2022, 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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