Surmodics Announces 24-Month Data from the SWING Trial Presented at VEITHsymposium

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Sundance™ Sirolimus Drug-Coated Balloon exhibits excellent safety profile

Primary patency maintained at 24 months in 71.4% of per protocol analysis population

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, announced today that 24-month data from the SWING Trial, a first-in-human study of the safety and performance of the Sundance™ Sirolimus Drug-Coated Balloon (DCB) was presented at the 50th annual VEITH Symposium in New York, New York.

The SWING Trial is a 35-subject prospective, multi-center, single-arm, feasibility study to evaluate the safety and performance of the Sundance Sirolimus DCB when used to treat occlusive disease of the infrapopliteal arteries. The SWING Trial enrolled subjects with stenotic or occluded lesions of the infrapopliteal arteries, a reference vessel diameter of 2 mm to 4 mm, and a total lesion length of ≤230 mm for treatment with the Sundance Sirolimus DCB at eight sites in Australia, New Zealand, and/or Europe. Study subjects will be followed for 36 months post index procedure.

The primary safety endpoint is defined as the number of subjects with a composite of freedom from Major Adverse Limb Event (MALE) and perioperative death at 30 days following the index procedure. The primary efficacy endpoint is the rate of late lumen loss at 6 months, as assessed by quantitative vascular angiography. Both primary endpoints of the SWING Trial were achieved.

Primary safety endpoint data showed no perioperative deaths or major amputations at 30 days, and just one major re-intervention was reported among the 35 trial subjects. The per protocol (PP) population reported an 8.3% rate of major adverse events (two clinically driven target limb revascularizations) at 6 months, with no additional adverse events reported for PP subjects in the 12 or 24-month data. Primary efficacy data show late lumen loss of 1.0 mm (±.79 mm) across 35 lesions at 6 months, indicating that the large luminal gain achieved immediately after the procedure was sustained post procedure.

Target lesion primary patency rate, defined as freedom from target vessel occlusion or target lesion revascularization associated with deterioration of Rutherford Clinical Classification and/or increase in size of pre-existing wounds (or occurrence of new wounds), and lesion restenosis >50%, was 71.4% at 24 months in the PP population. The Rutherford Clinical Classification describes 7 categories of peripheral artery disease, including both the patient's clinical symptoms as well as objective findings, and is used to assess disease progression.

"The two-year safety and performance results of the SWING trial continue to show promise for the Sundance Sirolimus DCB in treating below the knee disease in a challenging CLTI patient population where options are currently limited," said Professor Andrew Holden, MBChB, FRANZCR, EBIR, ONZM, Director of Northern Region Interventional Radiology Service (Auckland City Hospital, Auckland, New Zealand), co-lead investigator.

"We need to continue to strive for better treatments for treating infrapopliteal disease," added Professor Varcoe. "These results are promising and will inform future trials, which we hope will continue to advance improved treatments for our patients."

About the Sundance™ Sirolimus Drug Coated Balloon

The Sundance Sirolimus Drug-Coated Balloon utilizes a next-generation coating technology consisting of microcrystalline Sirolimus and a proprietary excipient designed to maximize drug transfer, enhancing Sirolimus delivery and sustaining therapeutic levels in the artery. Sirolimus, a potent anti-inflammatory and anti-proliferative compound, has been used successfully in coronary drug-eluting stents. The delivery of Sirolimus to the vessel wall during mechanical balloon dilatation provides an ancillary action of inhibiting the proliferation of cells, with the intended purpose of reducing restenosis. The Sundance Sirolimus Drug-Coated Balloon is not available for sale anywhere in the world, and currently is for investigational use only.

About Surmodics, Inc.

Surmodics is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention 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 modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is 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 beliefs and expectations regarding the Sundance™ Sirolimus Drug-Coated Balloon, 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 develop, obtain regulatory approval for, and commercialize our drug-coated balloon products; and (2) 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 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.

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