Surmodics Announces 12-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 12 months in 80% of per protocol analysis population

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 17, 2022-- Surmodics, Inc. (NASDAQ:SRDX) (the “Company”), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 12-month data from the SWING Trial, a first-in-human study of the Company’s Sundance™ Sirolimus drug-coated balloon (DCB) was presented at the 49th Annual Symposium on Vascular and Endovascular Issues (VEITHsymposium) in New York City.

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 infra-popliteal 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. They 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 8.0% 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-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 or Rutherford Clinical Classification and/or increase in size of pre-existing wounds (or occurrence of new wounds), and lesion restenosis >50%, was 80% at 12 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. To view the presentation, click here.

“Patient-reported outcome measures have continued to improve from baseline throughout the first 12 months for our modified intent to treat subject population,” said SWING Trial co-lead investigator Professor Ramon Varcoe, MBBS, MS, FRACS, PHD, MMed (ClinEpi). “The SWING Trial demonstrates that the Sundance Sirolimus DCB has tremendous promise and warrants evaluation in a large-scale pivotal trial.”

“Improvement in Rutherford Clinical Classification increased between the 1-month, 6-month, and 12-month endpoints, with significant clinical improvement demonstrated in 76% of per protocol subjects at 12 months,” added SWING Trial co-lead investigator Professor Andrew Holden, MD, MBChB, FRANZCR, EBIR, ONZM.

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 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 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 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 promise of the Sundance™ Sirolimus Drug-Coated Balloon and that it warrants evaluation in a large-scale pivotal trial, 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, 2021, 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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Surmodics Investor Inquiries
Jack Powell, Investor Relations
ir@surmodics.com

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