Surmodics Announces SWING Trial 24-Month Data to be Presented at VEITH Symposium on November 15

November 7, 2023 at 7:30 AM EST

35-subject SWING Trial evaluates the safety, performance of Surmodics' Sundance™ Sirolimus Drug-Coated Balloon

Updated safety and performance data for the SWING trial 24-month data will be shared

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 7, 2023-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, announced today that Professor Ramon Varcoe will present 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). The session will be held on Wednesday, November 15th, at the 50th annual VEITH Symposium in New York, New York.

TITLE: 2-Year Results With The Sundance DCB (Surmodics) To Treat BTK Occlusive Lesions: From The SWING Trial
DATE: Wednesday, November 15
TIME: 9:18 – 9:23 AM (EST)
VENUE: New York Hilton Midtown, Grand Ballroom East, 3rd Floor

Professor Varcoe, MBBS, MS, FRACS, PHD, MMed (ClinEpi), co-lead investigator of the SWING Trial, is a vascular surgeon at Sydney's Prince of Wales and Prince of Wales Hospital where he is Director of Operating Theatres, and Director of Surgery and Anesthetics for the South East Sydney Health District. He will review safety and performance data collected through 24 months of follow-up for 35 subjects with occlusive disease of the infra-popliteal arteries who were treated at study sites in Australia, New Zealand, and locations in Europe. Study subjects will be followed for 36 months after the index procedure.

Professor Varcoe previously presented SWING Trial 12-month data on January 18th at the 35th Annual International Symposium on Endovascular Therapy (ISET) conference. An 8.3% rate of major adverse events was reported in the per protocol (PP) population (two clinically driven target limb revascularizations) at 6 months, with no additional adverse events reported for PP subjects in the 12-month data. 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 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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