6-Month Data from the Surmodics SWING BTK First-in-Human Trial Presented at AMP Europe

October 11, 2022

Sundance™ Sirolimus DCB demonstrates lowest binary restenosis at 6 months compared to relevant BTK clinical trials

Excellent safety profile observed with no major amputations and low rates of MAE

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 11, 2022-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 6-month data from its SWING first-in-human (FIH) study of the company's Sundance™ Sirolimus drug-coated balloon (DCB) was shared at the Amputation Prevention Symposium (AMP) in Lugano, Switzerland.

The SWING study is a 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 study's 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. Data for the primary efficacy endpoint show a Late Lumen Loss (LLL) of 1.0 mm (± 0.79 mm) across 35 lesions at 6 months, indicating that the large luminal gain achieved immediately after the procedure was sustained six months post-treatment.

"At 6 months we observed a consistent improvement in Rutherford category and functional measures, as well as an excellent primary patency of 88.5%, which compares favorably to other drug coated balloons used in the infrapopliteal circulation," said SWING trial co-lead investigator Professor Ramon Varcoe, MBBS, MS, FRACS, PHD, MMed (ClinEpi).

The Swing Trial enrolled subjects with stenotic or occluded lesions of the infrapopliteal arteries, a reference vessel diameter (RVD) 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 multiple locations in Europe. They will be followed for 36 months following the index procedure.

"The novel coating on the Sundance Sirolimus DCB was evaluated in a challenging, predominantly CLI population with a high proportion of diabetes and moderate-severe calcification," said trial co-lead investigator Professor Andrew Holden, MD, MBChB, FRANZCR, EBIR, ONZM. "This first-in-human study demonstrates that the Sundance Sirolimus DCB could be a safe and promising treatment for occlusive disease of the infrapopliteal arteries."

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 beliefs and expectations regarding the Sundance™ Sirolimus DCB, 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 proprietary 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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