The Surmodics Sundance™ Sirolimus-Coated Balloon Catheter Earns FDA Breakthrough Device Status

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Sundance™ Sirolimus-Coated Balloon will receive prioritization throughout the FDA submission and review process to provide patients and physicians timely access to medical devices

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 29, 2019-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that the United States Food and Drug Administration (FDA) has designated its Sundance™ sirolimus-coated balloon (SCB) catheter as a Breakthrough Device under the Agency's Breakthrough Devices Program.

The program, launched in December 2018, is designed to streamline the market clearance/approval process for products that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The FDA has indicated that the goal of the program is to help patients and healthcare providers have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization.

The *Sundance* SCB has been designed to enhance the endovascular revascularization options for below-the-knee (BTK) arterial lesions in patients suffering from critical limb ischemia (CLI) and infrapopliteal arterial disease. CLI is a debilitating and life-threatening condition that will impact more than 3.5 million people by 2020. Patients with CLI commonly suffer from diminished quality of life and substantial overall health care needs. Reported 5-year mortality rates are greater than 50% and exceed those for every other form of occlusive cardiovascular disease. Without effective treatment following CLI diagnosis, approximately 25% of patients will not survive and 30% will face a major amputation within one year.

The *Sundance* SCB includes a proprietary drug-excipient formulation that utilizes the active ingredient sirolimus, a potent anti-inflammatory and anti-proliferative compound which 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* SCB is not available for sale anywhere in the world, and currently is for investigational use only.

No compelling therapeutic options exist for patients suffering from infrapopliteal disease. Interventions for patients with CLI are especially challenging due to the advanced stage of their disease. For the patient, an improvement in treatment outcomes may lead to improved quality of life, faster wound healing, reduced need for major bypass surgical intervention, and a decreased risk of amputation.

"The *Sundance* SCB is intended to address the unmet clinical need in patients with CLI and infrapopliteal arterial disease by providing a revascularization option with a proprietary sirolimus coating. This second platform adds to our stable of drug-coated balloon devices and furthers our effort to provide treatment solutions for the entire peripheral anatomy," said Gary Maharaj, Surmodics president and chief executive officer. "The *Sundance* SCB has the potential for improved outcomes in CLI patients over other available treatment options, and its availability is in the best interest of patients."

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 whole-product solutions that are designed to address unmet clinical needs for its medical device customers 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™ SCB, 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, 2019, 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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