Surmodics Announces First Patient Enrolled in IDE Study of SurVeil™ Drug-Coated Balloon

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EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Apr. 6, 2016-- Surmodics, Inc. (Nasdaq:SRDX), a leading provider of medical devices and in vitro diagnostic technologies, today announced enrollment of the first patient in an early feasibility study of its proprietary SurVeil™ drug-coated balloon (DCB). This study is part of the company's strategy to transform its medical device business from a provider of device coatings, to offering differentiated whole-product solutions to leading medical device customers.

Surmodics received investigational device exemption (IDE) approval for the study from the U.S. Food and Drug Administration (FDA) in late 2015. The *SurVeil* DCB includes the company's new, proprietary coating formulation for interventional vascular treatment of peripheral artery disease (PAD), and it is the first complete vascular medical device developed that will be clinically tested by Surmodics.

"First and second generation DCBs demonstrated a biologic effect and improved patency in patients with PAD," said Kenneth Rosenfield, M.D., section head, Vascular Medicine and Intervention at Massachusetts General Hospital, and chair of the Surmodics Scientific Advisory Board. "The new generation of DCBs, which includes significant advances in technology, provides a great opportunity to further enhance patient outcomes."

"We are pleased with the progress we made enrolling the first patient in this study of our proprietary *SurVeil* DCB," said Gary Maharaj, president and CEO of Surmodics. "We are proud to be on the path to offering highly differentiated whole-products solutions to our medical device customers."

Three clinical sites have been identified to participate in this early feasibility study for the *SurVeil* DCB. This study will include up to 15 patients and allow for the collection of data on product safety and usability before finalization of the product design. By undertaking this first-in-human early feasibility study of the *SurVeil* DCB in the U.S., Surmodics plans to gather meaningful data that could potentially accelerate future regulatory approvals.

About Early Feasibility Studies

U.S. medical device companies commonly conduct clinical trials abroad to expedite time to market. To encourage medical device innovation in the U.S., in 2013 the FDA introduced new guidelines under the early feasibility study program to facilitate the early clinical evaluation of medical devices in small numbers of human subjects. The guidelines allow companies to collect data on product functionality and safety before finalization of product design while still adhering to exacting human subject protections.

About Drug-Coated Balloons

Clinical trials have demonstrated the efficacy of DCBs in treating PAD. The collective results of these trials have demonstrated that DCBs lead to decreased late lumen loss – or increased lumen diameter – six months post intervention as compared to non-drug-coated balloons. In some cases, DCBs have also led to decreased need for recurrent intervention. DCBs often deliver paclitaxel, an antiproliferative drug, to arterial walls to limit restenosis which may reduce blood flow. The drug is usually combined with an excipient, which facilitates its transfer into the arterial wall.

Medical device manufacturers face significant challenges in optimizing DCB design. The aim of a DCB is to deliver the correct dosage of antiproliferative drug at the site of a lesion, and apply the drug uniformly to the arterial wall. To do this, the DCB must minimize unintended release of the drug into the blood stream during the procedure. Factors that may affect DCB performance include the ability of the excipient to preserve and release the drug at the appropriate time during the procedure, uniformity of the coating application on the balloon, and consistency of the paclitaxel drug on the balloon.

About the SurVeil™ Drug-Coated Balloon

The *SurVeil* DCB design incorporates Surmodics' decades of experience as a leading supplier of surface modification technologies to the medical device industry. It includes a Surmodics-proprietary drug-excipient formulation for the balloon coating, and a new and proprietary manufacturing process for the coating applications. It also includes the Surmodics Serene™ low-friction, low-particulate hydrophilic coating on the catheter shaft. The *SurVeil* DCB is not available for sale in the United States and is for investigational use only.

About Surmodics, Inc.

Surmodics is known as the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) tests and microassays. Following two recent acquisitions of Creagh Medical and NorMedix, the company is transforming its medical device business from being a provider of coating technologies, to offering whole-product solutions. The combination of proprietary coatings and application processes, along with enhanced device design, development and manufacturing capabilities will enable Surmodics to significantly increase the value it offers medical device customers. The company is focused on leading next-generation development of highly differentiated total vascular device solutions, designed and engineered to the most demanding requirements. Throughout its transformation, Surmodics' mission remains: to improve the detection and treatment of disease by using our technology to provide solutions to difficult medical device and diagnostic challenges. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the company, 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 company's strategy to transform to a provider of whole-product solutions, and the timing, impact and success of clinical development (including future regulatory milestones) of the Surmodics *SurVeil* 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 *SurVeil* DCB; (2) the possibility of unfavorable or delayed clinical trial results, whether the FDA and other relevant agencies will be satisfied with those results, even if favorable, and the impact on further trials and studies that will be required; and (3) other factors, including those identified under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2015, 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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