



Six-Month Data from the Surmodics SurVeil® Drug-Coated Balloon Early Feasibility Study Presented at VIVA 2017

September 13, 2017

- Study met primary endpoint and six-month secondary safety endpoints
- Results demonstrated primary patency of 100% and significant improvement in measured clinical outcomes

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Sep. 13, 2017-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies, today announced that data from the PREVEIL early feasibility study (EFS) of the company's SurVeil® drug-coated balloon (DCB) was shared in a late-breaking clinical trial presentation at the Vascular Interventional Advances (VIVA) 2017 conference in Las Vegas. PREVEIL is a prospective, U.S., multi-center, single-arm trial designed to assess the safety and feasibility of the SurVeil DCB in the treatment of subjects with symptomatic peripheral artery disease (PAD) due to *de novo* lesions of the femoral and popliteal arteries.

Gary Ansel, MD, system medical chief of the Vascular Program at OhioHealth, presented six-month results from 13 patients (Rutherford class 2 to 4) at 3 clinical sites who were treated with the SurVeil DCB. Average lesion length was 56 mm. Clinical assessments included primary patency and late lumen loss through six months, plasma paclitaxel levels, and changes in Rutherford classification, resting ankle brachial index/toe brachial index (ABI/TBI), 6-minute walk test, and walking impairment questionnaire (WIQ) at 1, 6, 12, 24 and 36 months. Key secondary safety endpoints included freedom from major vascular complications, evidence of paclitaxel toxicity, or thrombolysis in myocardial infarction (TIMI).

Data from the study show that acute success measures of safety were achieved in 100 percent of subjects. Results also showed primary patency of 100 percent and mean late lumen loss of 0.27 ± 0.54 mm at six months. Significant improvement in Rutherford classification, ABI/TBI, 6-minute walk test, and WIQ were seen at 30 days and six months. Median paclitaxel plasma concentration peaked immediately post-procedure (C_{max} 1.07 ng/mL) and was undetectable at 30 days. Secondary technical, device, and procedure success criteria were achieved.

"We are encouraged by the early patient data using the Surmodics SurVeil DCB platform and are excited to continue clinical evaluation of the product in the U.S. pivotal trial," said Dr. Ansel, who is a principal investigator in both the PREVEIL trial and the SurVeil DCB pivotal trial, TRANSCEND.

"Our goal with the SurVeil DCB is to improve drug transfer and effect on the arterial wall with a lower drug dose and a reduction in the amount of drug reaching tissue outside the area of treatment," said Gary Maharaj, president and CEO of Surmodics. "We are very satisfied with the results of the EFS and believe they are consistent with our encouraging pre-clinical data."

About the Surmodics SurVeil® DCB

In July 2017, Surmodics received an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA) to initiate a pivotal clinical trial of the SurVeil DCB. The randomized trial, TRANSCEND, will evaluate the SurVeil DCB for treatment for PAD in the upper leg compared to the Medtronic IN.PACT® Admiral® DCB. Surmodics expects to initiate enrollment in the TRANSCEND clinical trial in the fourth quarter of calendar 2017.

The design of the SurVeil DCB reflects Surmodics' long-standing industry leadership in the development of surface technology for vascular medical devices. The device includes a proprietary drug-excipient formulation for the balloon coating and is manufactured using a proprietary process to improve coating uniformity. Pre-clinical data have shown a three to five times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug concentrations compared to control DCBs.¹

The development of the SurVeil DCB is a major step forward in Surmodics' strategy to transform from a surface modification technology company to a provider of whole-product solutions for its medical device customers. In 2015, the company acquired Creagh Medical, an innovative developer and manufacturer of balloon catheters located in Ireland, and U.S.-based NorMedix, a manufacturer of differentiated specialty catheter and device delivery systems. Surmodics now has complete capabilities for design, development and high-volume manufacturing of a wide variety of highly differentiated balloon catheter solutions that utilize the company's advanced surface technology.

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) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total solutions, Surmodics' mission remains to improve the detection and treatment of disease. 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 SurVeil DCB and TRANSCEND clinical trial, including the expected initiation of that 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 *SurVeil* DCB, and other proprietary products; (2) our ability to achieve expected benefits from our acquisitions; and (3) 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, 2016, 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.

¹Surmodics data on file

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