Surmodics Completes Enrollment in Pivotal TRANSCEND Clinical Trial

August 28, 2019

Study designed to evaluate safety, efficacy of the company's next-generation SurVeil™ drug-coated balloon

Company Raises 2019 Revenue and EPS Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Aug. 28, 2019-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced it has completed enrollment in TRANSCEND, its pivotal clinical trial for the SurVeil™ drug-coated balloon (DCB).

"TRANSCEND is a rigorous level one, randomized controlled trial that comes at a very important time for the vascular and interventional community," said Kenneth Rosenfield, MD, a principal investigator of the TRANSCEND study. "By providing a head-to-head comparison with today's market leading DCB, this trial will provide data regarding the relative performance of the *SurVeil* DCB, which represents a new generation of DCB. Beyond the device itself, the new trial design will ultimately provide insight into clinically important questions regarding long-term results. There is great promise that this third-generation DCB will further improve upon current outcomes for this technology and provide additional benefit for clinicians and the patients that they treat."

The TRANSCEND trial enrolled 446 patients at 65 global sites. The randomized study will evaluate the safety and efficacy of the *SurVeil* DCB compared with a commercially available DCB in treating peripheral artery disease (PAD) in the upper leg. The results of the trial will also include long-term, patient-level data out to five years.

"I am excited about the potential of the *SurVeil* DCB to improve the treatment of PAD," said Professor Marianne Brodmann, a TRANSCEND Principal Investigator and the trial's leading enroller with 44 randomizations. "Our focus now shifts to follow-up and monitoring of these patients and the collection of high-quality data."

"Completing enrollment in the TRANSCEND trial marks an important milestone and brings us one step closer to bringing this next-generation treatment to PAD patients," said Gary Maharaj, Surmodics' president and chief executive officer. "I would like to thank our Principal Investigators—Dr. Kenneth Rosenfield, Professor Marianne Brodmann and Dr. William Gray—our trial advisor, Dr. Peter Schneider, and the entire Steering Committee for their leadership and guidance, all our investigators, support teams and, importantly, the patients we enrolled. Without their participation, we wouldn't be here today."

In February 2018, Surmodics entered into an agreement with Abbott (NYSE: ABT) that provided Abbott with exclusive worldwide commercialization rights for the *SurVeil* DCB. Pursuant to the terms of the agreement, Surmodics received a $25 million upfront payment and will receive a $10 million milestone payment in connection with the completion of patient enrollment in the TRANSCEND trial. Approximately $5 million from this milestone payment will be recognized as revenue in the Company's fiscal fourth quarter. Surmodics may earn an additional $57 million for other various product development milestones.

Upon the regulatory approval of the device, Surmodics will be responsible for manufacturing clinical and commercial quantities of the product and will realize revenue from product sales to Abbott as well as a share of profits resulting from sales to third parties.

2019 Guidance Update
With the completion of this milestone, Surmodics now expects fiscal 2019 revenue to be in a range of $97.0 million to $99.0 million, this compares to the Company's previous expected revenue range of $92.0 to $94.0 million. Surmodics is also increasing fiscal 2019 diluted GAAP EPS guidance to a range of $0.52 to $0.60 per share, compared with the Company's previous expectations of $0.24 to $0.32 per share. Diluted non-GAAP EPS is now expected to be in the range of $0.69 to $0.77 per share, compared with previous expectations of $0.41 to $0.49 per share.

About PAD
PAD is a serious and often underdiagnosed circulatory condition caused by a build-up of arterial plaque, most commonly in the legs. Drug-coated balloons are recognized as an important treatment option in treating PAD, which affects an estimated 200 million people worldwide.[1] Between 12-20 percent of Americans over 60 years old have PAD.[2] PAD increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.[3]

About the SurVeil™ DCB
The *SurVeil* DCB includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. Pre-clinical data have shown a more evenly transferred and durable drug effect, and lower incidence of downstream drug particles compared to the control drug-coated balloon.[4] The design of the *SurVeil* drug-coated balloon reflects Surmodics' industry leadership in the development of surface technology for vascular medical devices. The *SurVeil* DCB is not available for sale anywhere in the world and 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 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 certain statements about beliefs and expectations regarding the *SurVeil* DCB and the TRANSCEND clinical 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 obtain regulatory approval for and commercialize our *SurVeil* DCB; 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, 2018, 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.

References:

1. Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.
2. Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
3. National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.
4. Surmodics data on file

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Source: Surmodics, Inc.

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