Surmodics Provides Regulatory Update on its Strategy to Submit an Amended Premarket Approval Application for the SurVeil™ Drug-Coated Balloon

March 28, 2023

- *Announces Receipt of Positive Formal FDA Feedback via the Q-Submission Program*
- *Substantially reduces the anticipated time and cost needed to receive a PMA*

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Mar. 28, 2023-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that it has received formal feedback from the Food and Drug Administration (FDA; the Agency) related to its proposed approach to submit an amended premarket approval (PMA) application for the SurVeil™ drug-coated balloon (DCB).

Following the receipt of the FDA letter announced in the company's press release on January 19th, Surmodics has been focused on obtaining additional clarification and feedback from the Agency on the pathway and requirements to submit an amended PMA application for the SurVeil DCB in an approvable form. To this end, Surmodics prepared and submitted a Submission Issue Request (SIR), under the FDA's Q-Submission Program, to obtain the Agency's formal feedback on its proposed approach for addressing the FDA letter. The company has received written feedback from the FDA in response to its Submission Issue Request and completed a Submission Issue Meeting with the Agency to discuss the request and this written feedback.

In its verbal and written feedback, the FDA requested additional clarification related to already completed biocompatibility studies and revisions to the company's proposed labeling to amend the PMA application to put it into an approvable form. The FDA noted that the feedback it provided was based on the level of information included in the company's Submission Issue Request, and that the actual determination for the acceptability of the company's responses will depend on the information provided in company's formal amended PMA application to be filed with the FDA.

"We are delighted with our progress towards achieving a PMA for the SurVeil DCB," said Gary Maharaj, Chief Executive Officer of Surmodics, Inc. "The feedback from the FDA provides the necessary clarity on the process and content required to successfully amend our PMA application. Importantly, we do not anticipate the need for additional biocompatibility studies, which will significantly reduce our initial assumptions of the time and cost to amend our PMA application. With this alignment and clarity, we are preparing our amended PMA application for submission in the third quarter of our fiscal 2023 with a target of receiving premarket approval in the fourth quarter of our fiscal 2023."

About the SurVeil DCB and the TRANSCEND Clinical Study

The SurVeil DCB, a next-generation device for the treatment of peripheral artery disease (PAD), includes a proprietary drug-excipient formulation using an innovative process to improve coating uniformity. A presentation on the Intermediate-Term (24-month) Results of the TRANSCEND Study, presented by Kenneth Rosenfield, MD, MHCDS, is available on the Events & Presentation page of the Investors section of the company's website at https://surmodics.gcs-web.com. In the United States, the SurVeil DCB is an investigational device, limited by Federal law to investigational use.

About Surmodics, Inc.

Surmodics is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention 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 modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The company's mission is 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: regarding placing the amended PMA application for the SurVeil DCB in an approvable form, regarding the anticipated time and cost to receive a PMA for the SurVeil DCB, related to successfully amending the company's PMA application, about the company's anticipation of not needing additional biocompatibility studies, regarding the expected timing for submission of an amended PMA application for the SurVeil DCB and the target for receipt of premarket approval for the SurVeil DCB, and about the company's growth strategy, 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 the availability of Surmodics' personnel, and Surmodics' consultants to prepare and amended PMA application, the ability of the company and the FDA to reach a consensus on the appropriate labeling for the SurVeil DCB, the availability of FDA personnel to review an amended PMA, any further comments the FDA may have on an amended PMA, and 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, 2022, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at https://surmodics.gcs-web.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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