Surmodics Provides Regulatory Update Related to its FDA Premarket Approval Application for the SurVeil™ Drug-Coated Balloon

January 19, 2023 at 7:00 AM EST

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jan. 19, 2023-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced it has received a letter from the U.S. Food and Drug Administration (FDA; the Agency) related to its premarket approval (PMA) application for the SurVeil™ drug-coated balloon (DCB).

In the letter, the FDA indicated that the application is not currently approvable, while providing specific guidance as to a path forward. The letter stated that certain information within two general categories—biocompatibility and labeling—must be added by an amendment to the company's PMA application to place it in approvable form. Although the information identified by the Agency to put the PMA application in approvable form would require additional testing and analysis, the letter did not question the human clinical data submitted nor request any further human clinical data.

"We are disappointed by the FDA's response to our PMA application and continue to have confidence in our SurVeil DCB including its compelling performance in the TRANSCEND clinical study," said Gary Maharaj, Chief Executive Officer of Surmodics, Inc. "We are evaluating the issues raised in the FDA's letter and plan to meet with Agency representatives regarding its contents. Based on our discussion with the Agency, our team and external advisors will determine the appropriate path forward. Concurrently, we will be evaluating options to reduce our use of cash given this development. We expect to address these topics further in connection with our upcoming first quarter fiscal 2023 earnings call."

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 our 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 about the company meeting with the Agency, determining the appropriate path forward on the PMA application for the SurVeil DCB product, the company's intent to evaluate options to reduce its use of cash, and 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 FDA personnel, Surmodics' personnel, and Surmodics' consultants to address the FDA letter, limitations on Surmodics' ability to reduce its use of cash due to financial obligations of the company, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230119005185/en/

Surmodics Investor Inquiries:
Jack Powell, Investor Relations
ir@surmodics.com

Source: Surmodics, Inc.