Surmodics Receives FDA Approval for the SurVeil™ Drug-Coated Balloon

June 20, 2023

Surmodics to receive $27 million milestone payment from Abbott

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jun. 20, 2023-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced the receipt of U.S. Food and Drug Administration (FDA) approval for the SurVeil™ drug-coated balloon (DCB).

The SurVeil DCB may now be marketed and sold in the U.S. to physicians for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions (≤ 180 mm in length) in femoral and popliteal arteries having reference vessel diameters of 4 mm to 7 mm. The SurVeil DCB received CE Mark Certification in the European Union in June 2020.

“Obtaining FDA approval for our SurVeil DCB is one of the most important achievements in Surmodics’ history,” said Gary Maharaj, President and CEO of Surmodics. “It represents a major milestone in our efforts to develop next-generation products to help millions of people affected by peripheral artery disease and the physicians that treat them. I would like to thank our internal SurVeil DCB team and our external advisors, investigators and partners for their multi-year efforts to make this achievement possible.”

Abbott has exclusive worldwide commercialization rights for the SurVeil DCB. Surmodics will manufacture and supply the product and realize revenue from product sales to Abbott and a share of profits from Abbott’s third-party sales. Surmodics will also receive a $27 million milestone payment from Abbott. The company expects to recognize approximately $24.0 to $24.5 million of revenue related to the milestone payment in the third quarter of its fiscal year 2023.

Mr. Maharaj continued, “Building on our recent progress, Surmodics remains focused on supporting Abbott and its exclusive worldwide commercialization rights for the SurVeil DCB. We’ll discuss details on the developments and update our fiscal year 2023 financial guidance during our third quarter earnings call.”

“I am excited that the Surveil DCB will be available to treat patients in the US,” said Kenneth Rosenfield, M.D., co-principal investigator of the TRANSCEND clinical trial. “The Surveil DCB is the next generation DCB as established by results from the TRANSCEND trial which is the only head-to-head pivotal study that has been conducted vs the market-leading DCB. The Surveil DCB successfully demonstrated non-inferior safety and effectiveness at two years post-treatment with a substantially lower drug dose.”

SurVeil DCB TRANSCEND Trial Results Summary

24-month clinical trial results demonstrated the sustained durability of SurVeil DCB safety and efficacy outcomes.[1] SurVeil DCB remained non-inferior to market-leading IN.PACT® Admiral® DCB at a substantially lower drug dose. At 24 months:

- 81.8% of subjects treated with the SurVeil DCB met the secondary safety endpoint, a composite of freedom from device- and procedure-related death through 30 days post-index procedure and freedom from major target limb amputation (above the ankle) and clinically driven target vessel revascularization (CD-TVR) vs. 83.2% of subjects treated with the IN.PACT Admiral DCB.
- Less than 15% of patients in both arms of the trial required repeat revascularization procedures. One patient in the IN.PACT group required major leg amputation.
- Primary patency rate for SurVeil DCB subjects was 70.8% vs. 70.4% for IN.PACT Admiral.

Both the SurVeil and IN.PACT Admiral DCBs utilize paclitaxel drug coatings. However, the IN.PACT Admiral DCB has a 75% higher drug load of paclitaxel (3.5 µg/mm²) than the SurVeil DCB, which has a 2.0 µg/mm² drug load. The design of the SurVeil DCB is intended to provide more uniform drug distribution, better efficiency of drug transfer, and fewer downstream particulates and downstream emboli.

About the SurVeil DCB

The SurVeil DCB, a next-generation device that utilizes best-in-class technology in the treatment of peripheral artery disease (PAD), includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity.

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 Surmodics’

manufacture and supply of SurVeil DCB products and the potential product revenue the company may realize, the milestone payment the company expects to receive from Abbott and the amount and timing of revenue recognition related to the milestone payment, 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 actions of Abbott, the availability of components to manufacture SurVeil DCB products, the stability of SurVeil DCB manufacturing and sterilization processes at commercial scale, future accounting estimates related to the recognition of revenue from milestone payments, 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.

1. Rosenfield K. Intermediate-Term (24-Month) Results of the TRANSCEND Study Comparing a Next-Generation Paclitaxel Drug-Coated Balloon (SurVeil DCB) to IN.PACT DCB in the Treatment of Femoropopliteal Artery Disease. Presented at the 20th Annual VIVA (Vascular InterVentional Advances) conference; November 1, 2022; Las Vegas, Nevada.

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