Surmodics Receives CE Mark for its SurVeil™ Drug Coated Balloon

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Next generation device adds new technology to how physicians approach treatment of PAD

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Jun. 8, 2020-- 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 CE Mark Certification in the European Union for its SurVeil™ drug-coated balloon (DCB).

“I am excited about the potential of the SurVeil DCB to improve the treatment of PAD,” said Professor Marianne Brodmann MD, PhD, interventional cardiologist at Medical University Graz (Austria) and a Principal Investigator in TRANSCEND, Surmodics’ pivotal clinical trial for the SurVeil DCB. “Drug-coated balloons have been widely utilized in Europe as a frontline treatment for PAD."

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. Pre-clinical data have shown a more evenly distributed and durable drug effect, and lower incidence of downstream drug particles compared to the control drug-coated balloon.[1]

“This CE Mark is a critical milestone and an exciting step forward for Surmodics as we continue to demonstrate industry leadership in the development of pioneering vascular medical devices,” said Gary Maharaj, President and Chief Executive Officer of Surmodics. “The design of the SurVeil DCB reflects our dedication to providing innovative solutions that bring real clinical value – benefitting both clinicians and the patients that they treat. Congratulations go out to the entire Surmodics team on this well-deserved achievement.”

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 a $10 million milestone payment for the completion of patient enrollment in the TRANSCEND clinical trial. As a result of CE Mark attainment, Surmodics will receive an additional $10.8 million milestone payment. The company will recognize approximately $6.5 million as revenue in its fiscal third quarter and could earn up to an additional $45 million for future product development milestones. Surmodics is not forecasting material revenue from the sale of its SurVeil DCB product over the remainder of its fiscal year ending September 30, 2020.

Under the agreement, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue based on initial product sales to Abbott as well as a share of profits resulting from third-party sales. The SurVeil DCB is not available for sale and is for investigational use only in the United States.

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.[2] Between 12 to 20 percent of Americans over 60 years old have PAD.[3] 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.[4]

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 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 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 statements regarding milestone payments and revenues related to product sales, 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 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, 2019, 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. Surmodics data on file.
2. Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340.
3. Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
4. National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

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