



## 24-Month Data from Surmodics' TRANSCEND Trial Presented at VIVA 2022 Conference

November 2, 2022

*SurVeil™ Drug Coated Balloon (DCB) demonstrates sustained durability of safety, efficacy endpoints*

*SurVeil™ DCB non-inferior to market leading IN.PACT® Admiral® DCB at a substantially lower drug dose*

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 2, 2022-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 24-month data from its TRANSCEND clinical trial has been presented at the Vascular InterVentional Advances (VIVA) annual conference in Las Vegas.

The TRANSCEND trial randomized 446 patients at 65 global sites to assess the safety and efficacy of the SurVeil™ drug coated balloon (DCB) versus the IN.PACT® Admiral® DCB for treatment of superficial femoral and proximal popliteal artery lesions. TRANSCEND 12-month data, presented in January 2021, showed the SurVeil DCB met its primary safety and efficacy endpoints and was non-inferior to the market-leading IN.PACT Admiral DCB while utilizing a substantially lower dose of the anti-proliferative drug paclitaxel. Subjects in the TRANSCEND Trial will be followed for 60 months.

Data presented Tuesday by TRANSCEND trial principal investigator Dr. Kenneth Rosenfield, M.D., demonstrated comparable, sustained clinical outcomes between the SurVeil DCB and IN.PACT Admiral DCB cohorts through 24 months. Functional outcomes for treated patients also demonstrated continuous improvement at the two-year point. To view the presentation, [click here](#).

"These 24-month trial results validate the benefits that patients are experiencing after receiving treatment with the SurVeil DCB, and I am pleased to see that the SurVeil DCB continues to demonstrate excellent efficacy and safety in this pivotal RCT," said Dr. Rosenfield. "I'm excited about the potential of this next-generation DCB, which offers an attractive low dose therapeutic alternative to improve outcomes in our PAD patients."

At 24 months, 81.8% of subjects treated with 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 percent of subjects treated with the IN.PACT Admiral DCB. Fewer 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.

The TRANSCEND trial's two-year data showed a primary patency rate of 70.8% for SurVeil DCB subjects 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/mm<sup>2</sup>) than the SurVeil DCB, which has a 2.0 µg/mm<sup>2</sup> drug load. The design of the SurVeil™ DCB is intended to provide more uniform drug distribution, better efficiency of drug transfer, and fewer downstream particulate and downstream embolization.

"The TRANSCEND trial 24-month data demonstrate that clinically safe and effective outcomes with a substantially lower dose of Paclitaxel are achievable with the SurVeil DCB and reinforces the strength of Surmodics technology platforms and capability in vascular device innovation," said Gary Maharaj, President and CEO of Surmodics. "We are grateful to Dr. Rosenfield, co-principal investigators Marianne Brodmann, M.D. and William Gray, M.D. and all the physicians and research coordinators for their commitment to this important first of its kind clinical trial."

In February 2018, Surmodics entered into an agreement with Abbott (NYSE: ABT) that provided Abbott with exclusive worldwide commercialization rights for the SurVeil DCB. 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. The SurVeil DCB received CE Mark Certification in the European Union in June 2020.

### 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. In the United States, the SurVeil DCB is an investigational device, limited by Federal law to investigational use.

### 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](http://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 period during which subjects TRANSCEND clinical trial will be followed, the potential of the SurVeil DCB, Surmodics' potential responsibilities and revenues upon U.S. regulatory approval of the device, 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 changes to the schedule of the VIVA 2022 Conference, failure of the U.S. Food and Drug Administration to grant premarket approval for the SurVeil DCB, 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, 2021, 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](http://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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