Surmodics Announces Publication of TRANSCEND Trial, Highlighting Drug-Delivery Technology of its SurVeil™ Drug-Coated Balloon

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European Journal of Vascular and Endovascular Surgery Publishes Results Showing Comparable Safety and Efficacy of SurVeil™ DCB Despite IN.PACT™ Admiral™ DCB having 75% Higher Paclitaxel Dose.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Apr. 22, 2025-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced the publication of the TRANSCEND clinical trial, a global randomized study demonstrating the SurVeil™ drug-coated balloon (DCB) is non-inferior to the IN.PACT™ Admiral™ DCB for safety and efficacy in patients wit femoropopliteal arterial disease while using a substantially lower drug dose. The findings were published in the March 2025 edition of the European Journal of Vascular and Endovascular Surgery.[1]

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Figure 1. SurVeil™ DCB balloon coating (above) vs IN.PACT™ Admiral™ DCB balloon coatin (below).

Surmodics' leadership in drug-delivery technology dates to the company's development of the coating used on the first drug-eluding stent (DES), the Johnson & Johnson Cypher™ DESSurmodics leveraged its rich portfolio of scientific technology to develop the proprietary drug/excipient coating for the SurVeil DCB. This development program aimed to improve drug-delivery performance by enhancing drug retention during delivery to the treatment site, optimizing drug release and retention in the vessel wall, and maximizing drug bioavailability by carefully controlling the microcrystalline morphology of the coating. The uniform microcrystalline coating of the SurVeil DCB is observably different from the coatings of other DCBs (Figure 1). In addition, intense focus was placed on improving coating consistency and durability to minimize distal embolization of coating particulates. The ultimate goal was to produce a coating that minimized the drug dose on the balloon, while maintaining both a profound therapeutic effect and excellent safety profile. The TRANSCEND pivotal trial investigated this goal by comparing the Surmodics SurVeil drug-coated balloon with the market-leading IN.PACT Admiral DCB, which is a high-dose DCB.

Both the SurVeil and IN.PACT Admiral DCBs use coatings with the anti-proliferative drug paclitaxel. The SurVeil DCB has a uniform microcrystalline coating with a 2.0 µg/mm^2 drug load and is intended to enhance duration and optimize drug delivery. In contrast, the IN.PACT Admiral has a 75% higher drug load (3.5 µg/mm^2) than the SurVeil DCB. The SurVeil DCB, developed and manufactured by Surmodics, is marketed worldwide by Abbott.

Surmodics designed and conducted TRANSCEND, the first global head-to-head study of DCBs. The prospective, multi-center, single-blind, randomized, controlled TRANSCEND study compared the SurVeil DCB and the IN.PACT Admiral DCB for treating superficial femoral and proximal popliteal artery lesions. A total of 446 patients with femoropopliteal artery disease (Rutherford stages 2–4) were randomized to either the SurVeil DCB (n = 222) or the IN.PACT Admiral DCB (n = 224). Patients were enrolled at a total of 65 sites in 9 countries.

The primary efficacy endpoint of 12-month primary patency (freedom from binary restenosis or clinically driven target lesion revascularization) was comparable between the SurVeil DCB and the IN.PACT Admiral DCB (82.2% vs 85.9%). Similarly, the primary safety endpoint, defined as freedom from device or procedure-related death within 30 days and above-ankle amputation or clinically driven target vessel revascularization within 12 months, showed comparable outcomes (91.8% vs 89.9%). Non-inferiority was tested using a multiple imputation approach at one-sided alpha 0.025. Secondary outcomes through 24 months post-procedure were similar between the two groups, further demonstrating the non-inferiority of low-dose SurVeil DCB when compared to IN.PACT Admiral DCB. The company completed collection of 5-year follow-up data in 2024.

"The publication of TRANSCEND demonstrates its high quality of trial design, conduct, and interpretation of results, and establishes a strong evidence base for physician decision-making," said co-principal investigator Professor Marianne Brodmann, M.D., Head of the Clinical Division of Angiology at the Medical University of Graz, Austria. "Surmodics demonstrated confidence in its technology by choosing to conduct the first worldwide pivotal trial versus a high-dose device. The study's global patient enrollment lends added confidence to the generalizability of the results."

In addition to Professor Brodmann, Kenneth Rosenfield, M.D., Section Head for Vascular Medicine and Intervention at Massachusetts General Hospital, Boston; William Gray, M.D., System Chief, Division of Cardiovascular Diseases at Main Line Health, Philadelphia; and Peter Schneider, M.D., Professor of Surgery in the Division of Vascular & Endovascular Surgery at the University of San Francisco, were co-principal investigators of the TRANSCEND study.

"Peripheral artery disease affects more than 100 million people globally, causing chronic pain and disability while severely burdening healthcare systems," said Dr. Rosenfield. "To meet these challenges, we need PAD treatments with demonstrated long-term safety and effectiveness in maintaining lower limb blood flow. The TRANSCEND study shows that the SurVeil DCB is a best-in-class option for treating femoropopliteal arterial disease that minimizes patient exposure to antiproliferative agents."

"Surmodics' decision to execute a Level 1, head-to-head study against the market-leading DCB speaks to our conviction in the company's scientific know-how and differentiated technology," said Gary Maharaj, President and Chief Executive Officer of Surmodics. "We are grateful to Professor Brodmann, Drs. Rosenfield, Gray, Schneider, and all the physicians and research coordinators around the world for their commitment to this first-of-its-kind, groundbreaking clinical study. Special thanks go to Dr. Katharina Kurzmann-Gütl, whose exceptional efforts were instrumental to the study's publication."

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. The SurVeil DCB received CE Marking under the EU Medical Device Regulation (EU MDR 2017/745) in December 2023 and received FDA approval in the United States in June 2023.

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 the publication of TRANSCEND results establishing a strong evidence base for physician decision-making, and Surmodics' business 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 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, 2024, 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. Brodmann M, Gray WA, Schneider PA, et al. Results of SurVeil Versus IN.PACT Admiral Paclitaxel Coated Balloons in Femoropopliteal Arteries: 24 Month Outcomes of the Randomised TRANSCEND Study. Eur J Vasc Endovasc Surg. 2025;69(3):452-462.

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