6-Month Data From the Surmodics Avess™ AV Fistula DCB First-in-Human Study Presented at VIVA 2020

November 9, 2020

Study finds 100 percent target lesion patency at 30 days; 90.9 percent of patients free from revascularization at 6 months

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 9, 2020-- Surmodics, Inc. (NASDAQ:SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that 6-month data from the AVESS first-in-human (FIH) study of the company's Avess™ AV Fistula drug-coated balloon (DCB) was shared during a morning session at the Vascular Interventional Advances (VIVA) 2020 virtual conference.

The AVESS study is a prospective, multi-center, single-arm study to assess the safety and performance of the Avess DCB when used in the treatment of subjects with obstructive lesions of arteriovenous fistulae (AVF) for hemodialysis.

Six-month data from the study show that target lesion patency at 30 days and 6 months was 100 percent and 90.9 percent, respectively. A single re-intervention was required within 6 months, with no AVFs thrombosed. The study's primary safety endpoints reported no mortality and no device or procedure related adverse events at 30 days, and all patients maintained functional AVFs for hemodialysis.

"This first-in-human study demonstrates that the Avess DCB is a safe and promising treatment for AV fistula stenosis, which can lead to vascular access dysfunction, thrombosis and loss," said Ramon L. Varcoe, MD, MBBS, MS, FRFRACS, PhD, associate professor of vascular surgery at Prince of Wales Hospital (Sydney, New South Wales, Australia) and co-lead investigator for the AVESS FIH clinical study.

"Previous AV fistula studies have demonstrated that DCBs effectively reduce rates of restenosis after percutaneous angioplasty," added Andrew Holden, MD, MBChB, FRANZCR, EBIR, ONZM, Associate Professor, Director of Interventional Radiology at Auckland City Hospital (Auckland, New Zealand) and co-lead investigator for the AVESS FIH clinical trial. "The Avess DCB is a next-generation DCB that may provide further clinical benefits while minimizing systemic paclitaxel exposure."

Data presented include 6-month results from 12 patients treated with an Avess DCB between December 2018 and August 2019. The majority of AVFs were radiocephalic (10/12, 83.3 percent) with the stenosis located in the juxta-anastomosis (7/12, 58.3 percent), cannulation zone (2/12, 16.7 percent) and outflow (3/12, 25 percent). All patients completed follow-up at or beyond 6 months.

"Our goal with all of our DCB platforms has been to advance the technology to improve drug transfer and distribution effect on the arterial wall offering the opportunity to use a lower drug dose," said Gary Maharaj, president and CEO of Surmodics. "We are quite pleased with the AVESS first-in-human study results, which provide vital safety data on the Avess DCB and directional data on its effectiveness. This FIH data strengthens our believe that the Avess DCB could be a safe and promising treatment that improves patient outcomes while reducing the number of interventions needed to maintain patency."

About the Avess DCB

The design of the Avess DCB reflects Surmodics' long-standing industry leadership in the development of surface technology for vascular medical devices. The device includes a proprietary drug-excipient formulation for the balloon coating and is manufactured using a proprietary process to improve coating uniformity. Pre-clinical data have shown a three to five times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug concentrations compared to control DCBs.[1] The Avess DCB is an investigational device, limited by United States 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. 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 potential clinical uses of the Avess DCB 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 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

View source version on businesswire.com: https://www.businesswire.com/news/home/20201109005326/en/

Surmodics, Inc.
Tim Arens, 952-500-7000
ir@surmodics.com

Source: Surmodics, Inc.