Surmodics Announces Early Results from PROWL Registry Study of Real-World Limb Ischemia Patients Treated with Pounce™ Thrombectomy System

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Early subset analysis of 60 patients with acute, subacute, or chronic symptoms of limb ischemia demonstrated 96.8% procedural flow restoration, with 81.7% of subjects not receiving additional thromboemboli removal treatment post Pounce™ System use.

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Oct. 30, 2024-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the health care industry, today announced that early results of a subset of 60 real-world acute, subacute, and chronic limb ischemia patients from its PROWL registry study were presented by Dr. Dean Ferrera at the 36th Annual TCT Symposium in Washington, D.C.

PROWL is an open-label, retrospective, multi-center, U.S. registry of the Surmodics Pounce™ Thrombectomy Platform for the non-surgical removal of emboli and thrombi in the peripheral arterial vasculature. The registry is collecting real-world efficacy and safety outcomes data for endovascular interventions using the fully mechanical, non-aspiration-based Pounce Thrombectomy Platform for up to 500 patients at up to 30 sites. The core lab-adjudicated study is enrolling all patients treated with the Pounce Platform, including those with shortened life expectancy, history of cancer or COVID-19, and those with prior interventions to the target limb. Dr. Ferrera, on behalf of the PROWL investigators and National Co-Principal Investigators Dr. Sean Lyden, Chairman of the Department of Vascular Surgery, Cleveland Clinic, and Dr. Joseph Campbell, Interventional Cardiologist, OhioHealth, presented results from the infrainguinal PROWL subset. All patients in the 60-patient subset analysis were treated with the Pounce Thrombectomy System, indicated for use in peripheral arteries 3.5-6 mm in diameter.

The analysis examined subjects with symptomatic native, infrainguinal vessels, followed through 30 days. Procedural success, defined as restoration of pulsatile flow in the target lesion(s) with or without adjunctive treatment (patient level success), was 90.0%. Nearly all (96.8%) of subjects experienced final post-procedural TIPI 2-3 blood flow restoration. Technical success, defined as restoration of blood flow to the target lesion(s) with <50% residual obstruction without the need to initiate catheter-directed therapies or to proceed to open surgery or other endovascular thrombectomy devices (lesion-level success), was 80.8%. Of the 60 subjects, 49 patients (81.7%) received no further thromboemboli removal treatment within 30 days post Pounce™ System use. Product use was well tolerated, with only 1 subject (1.7%) experiencing device-related adverse events.

Previous studies of aspiration thrombectomy for symptomatic limb ischemia excluded patients with symptom duration greater than 14 days[1,2] or patients whose thrombi or emboli were not fresh.[3] In the 60-patient PROWL cohort, 60.0% of patients presented with acute (≤14 days) limb ischemia, 16.7% with subacute (15-28 days) limb ischemia, and nearly 1 in 4 (23.3%) presented with chronic (>28 days) limb ischemia. Forty patients (66.7%) in the 60-patient cohort avoided an ICU admission, while 49 (81.7%) were discharged home.

“Although patients with limb ischemia often seek care acutely, many patients present after experiencing symptoms for several days or weeks,” said Dr Campbell. “As a result, operators are often challenged to remove clots of mixed morphology and chronicity, which may impact procedural success rates both with thrombolytic and primary aspiration strategies. These early PROWL results suggest that the Pounce Thrombectomy System is effective as a standalone solution for removing acute-to-chronic clot in real-world clinical settings without use of adjunctive thrombolytics, aspiration devices, or surgery.”

“In terms of health care resource utilization, the high rate of ICU avoidance and discharge home in this very ill population is encouraging. We’re eagerly awaiting further results from this highly promising registry study,” he added.

About the Pounce Thrombectomy Platform

The Pounce Thrombectomy Platform comprises the Pounce Thrombectomy System, Pounce LP (Low-Profile) Thrombectomy System, and the Pounce XL Thrombectomy System. All are FDA-cleared, fully mechanical thrombectomy devices designed to promptly remove organized thrombus or embolus without the need for thrombolytics, aspiration, or capital equipment. They are indicated for use in peripheral arteries 3.5-6 mm, 2-4 mm, and 5.5-10 mm in diameter, respectively. The Pounce XL Thrombectomy System is currently pending commercial release.

Described as “grab-and-go” solutions, Pounce Thrombectomy Platform devices are both readily deployable and simple to use. The systems are composed of three components: a delivery catheter, a basket wire, and a funnel catheter. The basket wire is delivered via the delivery catheter distal to the location of the thrombus, deploying two nitinol self-expanding baskets. The baskets capture the clot and are retracted into the nitinol collection funnel. With the clot entrained, the system is withdrawn into a minimum 7 Fr guide sheath through which the clot is removed from the body.

About Acute Limb Ischemia (ALI)

ALI is characterized by a sudden decrease in arterial perfusion to the limb, with a potential threat to limb survival, requiring urgent evaluation and management. Common causes include embolization due to cardiac dysrhythmia or thrombus from pre-existing peripheral artery disease.[4] ALI is associated with 30-day amputation and mortality rates as high as 30% and 11.5%, respectively.[5] ALI-related interventions may account for up to 16% of the case volume for vascular surgeons and be accompanied by hospitalization costs of $26,000–$29,000.[5] Interventional radiologists and interventional cardiologists also treat ALI.

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 Securities and Exchange Commission.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including the statements regarding the potential number of patents and sites for the PROWL registry study, that the early PROWL results suggest that the Pounce Thrombectomy System may be effective as a standalone solution for removing acute-to-chronic clot in real-world clinical settings without adjunctive treatments, and regarding Surmodics' 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 outcome of the full PROWL registry study, 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, 2023, 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.

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