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VentureMed Completes Enrollment of the FLEX Vessel Prep™ System FLEX First AV Registry For The Treatment of Arteriovenous (AV) Access Management

Minneapolis, Minnesota, July 30, 2024 - VentureMed Group, Inc., a privately held medical device innovator in access management for arteriovenous (AV) fistulas and grafts and vessel preparation for interventional treatment of peripheral arterial disease (PAD) announced it has completed enrollment of The FLEX First AV Registry.

This "FLEX First" AV Registry was designed to treat subjects with AVF/AVG stenosis to demonstrate The FLEX Vessel Prep™ System combined with balloon angioplasty will improve the rate of target lesion primary patency as compared with comparable published rates of balloon angioplasty alone. This study also emphasized and encouraged enrollment of Black/African-American and female subjects to insure data generation for historically underserved patient populations and in keeping with enrollment profiles achieved in previous VentureMed, AV Access studies. The study was a prospective, multi-center study in 4 sites and treated 130 patients. The primary endpoint is target lesion primary patency with patient follow-up at 6- and 12-month intervals.

"Dialysis access requires constant maintenance due to its high natural failure rate," said Ari Kramer, MD, Primary Investigator and Chief of AV Surgery and Interventions at Spartanburg Regional Medical Center. "I've seen firsthand how the FLEX system can transform patient care. By reducing balloon pressures by one-third to one-half in many cases, FLEX can make procedures more durable, less traumatic, and less painful. This isn't just about technology; it's about improving the lives of dialysis patients, helping them endure fewer interventions and experience a better quality of life."

The FLEX Vessel Prep System has a unique non-balloon-based mechanism of action that creates longitudinal micro-incisions that release circumferential tension in diseased vessels. This release of tension is how FLEX modifies AV stenoses to potentially improve and extend patency with therapeutic treatments (PTA, DCB etc.), and may reduce complications and vessel trauma including severe dissections that can lead to bail-out stenting. The FLEX Vessel Prep System is also indicated for in-stent restenosis (ISR).

"The completion of this study comes at a very exciting time for VentureMed as we just recently received our transitional pass through payment (TPT) from CMS ," said Denis Harrington, president, and chief executive officer of the VentureMed Group. "We will add this data to our existing body of strong, published clinical evidence that demonstrates substantial clinical improvement over the existing standard of care (plain ballon angioplasty) and corresponding economic value for our customers."

About VentureMed Group, Inc. and the FLEX Vessel Prep System

The VentureMed Group, Inc. develops and markets innovative endovascular medical devices to solve unmet medical needs in the treatment of stenoses of AV fistulas and grafts and PAD. The FLEX VP System is a unique, non-balloon-based approach to optimizing revascularization by creating long controlled-depth micro-incisions that release circumferential tension to improve vessel compliance and enable luminal gain with less vessel trauma that may cause restenosis. FLEX was designed to provide controlled and predictable pre-treatment to optimize outcomes in complex stenoses & lesions of any length or vessel morphology. The FLEX VP System received CE Mark and 510(k) clearance from the US Food and Drug Administration.

For more information, visit www.VentureMedgroup.com.