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VentureMed announces First patient Enrolled in the FLEX First AV Registry For The Treatment of Arteriovenous (AV) Access Management

Minneapolis December 15, 2022 – 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 today that Sanford Altman, MD, Founder and Medical Director, Open Access Vascular Access, Miami, FL treated the first patient in the FLEX First AV Registry. The FLEX Vessel Prep™ System is VentureMed's AV and PAD product designed to create longitudinal micro-incisions that release circumferential lesion tension allowing lower balloon inflation pressures and potentially enhancing drug delivery with drug eluding therapies that synergistically improve patency and time between interventions.

The first patient treated was part of VentureMed's second AV Registry. This "FLEX First" AV Registry is 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 will also emphasize and encourage 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 will take place in up to 15 sites and treat up to 400 patients. The primary endpoint is target lesion primary patency with patient follow-up at 6- and 12-month intervals.

"Maintaining AV Access in end stage renal disease patients can be challenging", said Sanford Altman, MD., "Prolonging access patency is always the goal for these patients; however, this is not often easily achieved. We are excited about utilizing the FLEX Vessel Prep System in hopes that it will extend our patients access patency allowing them more time between interventions."

The FLEX Vessel Prep System has a unique non-balloon-based mechanism of action that creates longitudinal micro-incisions that may 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).

"We are excited to add another study to our continued growing body of clinical evidence," said Denis Harrington, chief executive officer and president of VentureMed. "We are committed to expanding evidence that demonstrates the clinical benefit of utilizing FLEX Vessel Prep to potentially enhance outcomes

and extend patency across the full spectrum of End Stage Kidney Disease (ESKD) patients that require interventional procedures to maintain life-saving dialysis treatment."

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 that may 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.**