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VentureMed Completes Enrollment of FLEX Vessel Prep™ System Randomized Control Trial in Arteriovenous Fistulas

Minneapolis, Minnesota, May 24, 2021 - 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 it has completed enrollment of a randomized clinical trial (RCT) titled "FLEX Vessel Prep Prior To PTA for the Treatment of Obstructive Lesions in the Native AVF". This RCT was conducted to assess primary patency at 6 months when using FLEX Vessel Prep System prior to PTA vs. PTA alone for the treatment of obstructive lesions of native arteriovenous fistulae in the upper extremity. Dialysis patients average 1.9 interventions per year to maintain access and continue lifesaving hemodialysis treatment. Opportunities for better outcomes and to extent the time between interventions are good for patients and save money for healthcare systems.

The FLEX RCT study was a prospective, multi-center, randomized study conducted in 7 sites across the United States. Seventy-five patients were enrolled and includes 30-day, 3 month and 6-month follow-up.

"Although fistula are the preferred access for hemodialysis, fistula dysfunction and failure remains a significant issue in AV dialysis access care. Balloon angioplasty considered the gold standard by most, still has its limitations due to the resistant and recurrent nature of these hyperplasic lesions, often requiring the use of high-pressure balloons," said Sanford Altman, MD, Open Access Vascular Access in Miami Florida. "These high-pressure balloon treatments can cause vessel wall damage accelerating restenosis and shortening the time between interventions. By utilizing the FLEX Vessel Prep prior to angioplasty, we are hoping to see improved vessel compliance, reducing the need for high pressure balloons while reducing the barotrauma to the vessel wall thereby extending the primary patency and time between interventions."

"This RCT builds upon the rich and diverse data we are gathering for the FLEX system. The rapid enrollment of these 75 patients at 7 US centers during a COVID surge is encouraging", said Denis Harrington, president, and chief executive officer of the VentureMed Group. "We are excited to report our previous study, The FLEX AV Registry, will be presented at the VASA 2022 Symposium June 6-9th in Charleston, South Carolina. 2022 is becoming a very impressive year for FLEX Vessel Prep".

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.