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FLEX Vessel Prep AV Registry Data Shows A Longer Lasting Solution to Stand Alone PTA When Treating AV Access Fistulas and Grafts

Minneapolis, MN, June 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 data presented at the Vascular Access Societies of the Americas (VASA) June 9-11, Charleston, South Carolina.

Study Details and Findings

FLEX Vessel Prep™ System AV Registry Clinical Study
Single-arm, prospective study in 8 US centers
Conducted with 114 real world patients

“AV Access failure is a significant issue for patients that interrupts lifesaving hemodialysis treatments, so physicians are always searching for new options to extend time between interventions”, said John Aruny, MD, Primary Investigator, Dialysis Access Institute, Orangeburg, SC. “The FLEX AV Registry 6-month outcomes demonstrate sustained patency across most patients and really impressive results in the Cephalic Arch and AV Grafts over treating with PTA alone.”

6 Month Functional Patency Results with FLEX Vessel Prep: Freedom from target lesion revascularization (FFTLR)

- 71% patency for all AV Fistula (AVF) patients – 219 days FFTLR, compared with historical data ranging from 21.3 to 55%¹.
- 69% patency for Cephalic arch lesions – 211 days FFTLR, compared with historical data of 8-52%¹.
- 47% patency for all AV Graft (AVG) patients – 174 days FFTLR, compared with historical data of 6-34%¹.

The FLEX Vessel Prep procedure demonstrated excellent safety in the AV Registry with no serious adverse events reported.

This AV Registry also set a new standard for patient diversity and inclusivity as more than 65% (75/114) of the patients enrolled were African American patients. The 6-month safety and patency results for African American patients treated with FLEX Vessel Prep were equal to or better than the total patient pool for all recorded measurements.

“This real-world data continues to build strong evidence that the FLEX Vessel Prep System is a safe and very effective vessel preparation tool in AV Access over PTA alone,” said Denis Harrington, chief executive officer and president of VentureMed. “This real world, all-comers registry featured an extremely challenging cohort of AV access patients. The FLEX AV procedure extended time between interventions for these highly compromised patients undergoing life saving hemodialysis therapy. VentureMed is committed to creating technologies

that help extend time and reduce complications for end state kidney disease patients and generating clinical evidence to demonstrate these improvements.”

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.

¹Historical comparative data on file