Flow Forward Reports Multiple Studies on its Novel Approach to Improving Vascular Access for Hemodialysis Patients

Results Highlighted at VEITH Symposium and ASN Annual Meeting

OLATHE, Kan. – February 9, 2017 - Flow Forward Medical Inc. (Flow Forward), an early-stage company focused on improving outcomes for hemodialysis patients through the rapid creation of high-quality vascular access sites, today announced the completion of a preclinical study and a computational fluid dynamics (CFD) study supporting continued development of the Company's Arteriovenous Fistula Eligibility (AFE) System™. The AFE System is a small external blood pump designed for temporary use to stimulate flow-mediated vein dilation to make more hemodialysis patients eligible for creation of arteriovenous fistula (AVF) and arteriovenous graft (AVG) vascular access sites, and to increase success rates after AVF and AVG surgeries.

In the nonclinical study, supported by Small Business Innovation Research (SBIR) Grant R43DK105631 awarded to Flow Forward by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH), ovine cephalic veins were treated for six days with the AFE System. Maximum vein diameter increased on average 89 percent from 5.5 mm to 10.4 mm with treatment. At the time of AVF creation, outflow cephalic veins were of larger average diameter in AFE System-assisted AVFs than in control AVFs, while inflow brachial arteries had similar diameters. After six weeks, both inflow arteries and outflow veins were larger in AFE System-assisted AVFs than in control AVFs, suggesting improved AVF maturation. An independent analysis of outflow veins of the arteriovenous fistulas (AVFs) created using the pre-treated veins demonstrated an average blood flow rate 398 percent higher than AVFs created using untreated veins (1712 mL/min versus 344 mL/min) after six weeks of maturation. An independent histology review of these AVFs at six weeks indicated the average cross-sectional area of AVF inflow arteries and outflow veins was 10.6 mm^2 and 200 mm^2, respectively, for pre-treated AVFs, and 5.3 mm^2 and 86 mm^2, respectively, for control AVFs.

"These data further validate the rapid rate of vein dilation during AFE System treatment. We now believe that 7 to 14 days of treatment is likely to be enough for most patients," said President and CEO F. Nicholas Franano, MD. "This study also suggests that the overall rate and time required for AVF maturation, and the duration of primary and secondary AVF patency are likely to be positively affected by the treatment of veins with the AFE System prior to AVF surgery." Some preliminary results from this study were presented on November 19, 2016 at the 43rd Annual VEITH Symposium in a presentation titled "Innovation in Vascular Access: Where Are We Headed?"

Flow Forward also announced today the completion of a computation fluid dynamics (CFD) study in partnership with the research group of Dr. Yan-Ting Shiu in the Division of Nephrology & Hypertension at the University of Utah. This study used bench flow loops and CFD modeling to compare blood flow, pressure, wall shear stress (WSS), wall motion in AVF and AFE System outflow veins, and determined the effect of outflow vein diameter on these important biomechanical factors. A summary of this study was presented in a poster at the American Society of Nephrology (ASN) Annual Meeting on November 19, 2016.

Elevated wall shear stress (WSS) stimulates AVF outflow vein dilation during AVF maturation, increasing the likelihood of successful AVF use for hemodialysis. However, this elevated WSS may demonstrate a "Goldilocks effect", such that when elevated WSS levels are not high enough, vein dilation is inadequate or slow and when WSS levels are too high, vein walls can be damaged. The study carried out by Flow Forward and the University of Utah suggests that peak WSS levels are very high in AVF outflow vein segments

adjacent to the anastomosis, indicating a high likelihood of vein wall damage. This effect was especially pronounced with small veins, which is consistent with the recent finding that 86% of forearm AVFs failed to mature at six weeks without intervention seen in the recent Human Fistula Maturation study funded by the National Institutes of Health (NIH). In the Flow Forward study, WSS levels were also elevated in AFE System outflow veins, but peak WSS levels were much lower than with AVF, indicating a lower risk of vein wall damage.

Cyclic stretching of venous smooth muscle cells has also been implicated in AVF failure. This study also suggested that AVF outflow vein segments adjacent to the anastomosis experience cyclic stretching due to the pulsatile nature of the blood flowing from the inflow artery, with the greatest amount of displacement and stretch seen with the smallest AVF outflow veins. Conversely, due to the non-pulsatile nature of the blood flowing from the AFE System, there is no cyclic stretch of the outflow vein wall.

“We believe developing a better understanding of the causes of AVF failure can aid in the development of medical devices and treatment methods to increase AVF maturation success, and primary and secondary AVF patency rates,” said Dr. Franano. “It is encouraging to see that the AFE System can consistently deliver optimal doses of wall shear stress to veins using non-pulsatile blood flow, providing an ideal environment for rapid vein maturation.”

About Hemodialysis and Vascular Access Failure
Hemodialysis is a lifesaving treatment for more than 2.3 million patients worldwide with end-stage renal disease (ESRD). Before patients can receive hemodialysis, a reliable vascular access site must be created. An AVF, which surgically connects an artery to a vein, typically in the arm, is preferred over other forms of vascular access due to improved patient survival, reduced complications and hospitalization rates, and large reductions in the cost of care. However, nearly 40 percent of U.S. hemodialysis patients do not currently use an AVF for vascular access, primarily due to inadequate vein diameter and high rates of AVF failure (up to 60 percent) following conventional surgical placement. There are currently no products approved by the U.S. Food and Drug Administration (FDA) to increase AVF eligibility or enhance unassisted AVF maturation, the process by which an AVF becomes ready for hemodialysis.

About Flow Forward Medical
Flow Forward is developing a novel approach to rapidly establish high-quality vascular access sites for hemodialysis. Our AFE System comprises a small external blood pump designed for temporary use to stimulate flow-mediated vein dilation to make more patients eligible for an AVF and increase success rates after surgery. Establishment of a reliable AVF reduces morbidity and mortality in hemodialysis patients, as well as the overall cost of care. For additional information, please visit www.flowforwardmedical.com.

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