BD Announces Enrollment in Post-Market Studies of the WavelinQ™ Arteriovenous Endovascular Fistula

FRANKLIN LAKES, N.J., April 29, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced today that enrollment has begun and the first patients have been treated in the post-market surveillance study, CONNECT-AV.

CONNECT-AV is a prospective, single-arm, open-label study that will follow patients treated with the WavelinQ™ EndoAVF System for 24 months.

The study's dual primary effectiveness endpoints are the percentage of subjects dialyzing using successful 2-needle cannulation for at least 75% of the dialysis sessions over a continuous 28-day period at 6 months, and the subjects maintaining primary patency at 6 months.

The primary safety endpoint is freedom from device and procedure-related serious adverse events through 30 days. The trial is expected to enroll 280 participants in the United States.

"For more than 50 years, medicine has looked for a next generation hemodialysis access procedure for patients with ESKD that can truly change the treatment paradigm," said Brandon Repko, MD, Medical Director of Nuclear Imaging and Therapeutic Services at Butler Memorial Hospital in Butler, Pennsylvania, who treated the first patient in the CONNECT-AV trial in March 2021. "The CONNECT-AV trial is the next step in proving WavelinQ™ EndoAVF System's role in 21st century AV fistula creation. My colleagues and I are thrilled to be a part of that patient care evolution."

CONNECT-AV is one of two post-market studies of the WavelinQ™ EndoAVF System. The second study, WAVE-Global is a prospective, single-arm, open-label study that will follow patients treated with the WavelinQ™ EndoAVF System for 24 months.

The WAVE-Global primary endpoints are the number of interventions needed post creation to facilitate and/or maintain AV fistula use at 6 months, and the proportion of participants with freedom from Clinical Events Committee adjudicated device- or procedure-related serious adverse events at 30 days. The trial is expected to enroll 150 participants globally (outside of the United States).

"Physicians already have real-world experience using the WavelinQ™ EndoAVF System to create AV fistulas that make life-preserving hemodialysis possible," said Panagiotis M. Kitrou MD, MSc, PhD, EBIR, FCIRSE, Asst. Professor in Interventional Radiology, Patras University Hospital, Greece and a principal investigator in the WAVE-Global study. "Both of these studies will provide important long-term data on the safety and effectiveness of WavelinQ™ EndoAVF System to help make informed decisions about patient care."

The first patient in the WAVE-Global trial was treated by Dr. Kitrou in December 2020 at Patras University Hospital.

Globally, there are approximately 3 million patients on hemodialysis with the majority depending on an AV fistula as their lifeline for hemodialysis therapy[i]. The WavelinQ™ EndoAVF System is designed to give healthcare providers a versatile endovascular AV fistula creation alternative to open surgery. It uses two thin, flexible, magnetic catheters and a burst of RF energy to create an endovascular AV fistula.

Using the WavelinQ™ EndoAVF System gives physicians a minimally invasive option for creating an AV fistula for patients who need hemodialysis to survive. The system's 4F, low profile increases anatomical fistula location options and enables additional venous wrist access points (ulnar vein or radial vein), providing increased procedural flexibility for physicians, while helping to reduce risk of scarring or arm disfigurement for patients compared to open surgical AV fistula creation.

"WavelinQ™ EndoAVF System represents a major advancement in AV fistula creation and offers physicians and their patients an innovative and minimally invasive alternative to surgical AV fistula creation, which can be associated with scarring and vessel trauma," said J.D. Meler, MD, Vice President of Medical and Clinical Affairs for BD's Peripheral Intervention business. "As innovators in this space, the CONNECT-AV and WAVE-Global Studies are part of our ongoing effort to add data to help inform physicians, payors and regulators about the value and utility of the WavelinQ™ EndoAVF System and how it may benefit patients who require hemodialysis."

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process

for health care providers. BD and its 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

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The WavelinQ™ EndoAVF System is indicated for the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

[i] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. BD-29250 v2

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