Avenu Medical Receives FDA Approval for Ellipsys Vascular Access System for Non-Surgical Dialysis Fistula Creation

Breakthrough Endovascular Arteriovenous Fistula (endoAVF™) Technology Approved for Hemodialysis Access

San Juan Capistrano, CA, USA – June 26, 2018 – Avenu Medical, Inc. announced today that it has received De Novo marketing authorization from the Food and Drug Administration (FDA) to market its Ellipsys® Vascular Access System, an innovative, minimally-invasive catheter-based system designed for End-Stage Renal Disease (ESRD) patients requiring hemodialysis.

The FDA's action will provide U.S. physicians and patients access to a unique non-surgical option for arteriovenous (AV) fistula creation, a procedure that has not changed in over 50 years.

"Good vascular access makes a tremendous difference in patient outcomes," said long time kidney patient advocate Terry Litchfield. "This revolutionary non-surgical fistula creation can reduce the pain and suffering associated with traditional fistula surgery, lessen failed surgeries and reduce catheter time for patients."

Since 1966, the AV fistula has been surgically created in an operating room by sewing a vein and an artery together, usually in the arm. When this is done, blood from the artery will pass through the vein increasing its flow rate and diameter. This makes the vein suitable for the insertion of the needles required for hemodialysis treatment. An AV fistula is the preferred method for vascular access as there is evidence of longer term patency, improved flow rates and fewer complications than other methods of vascular access.

A game-changing innovation for dialysis patients and clinicians, Avenu's endoAVF technology, Ellipsys is a less-invasive alternative to the traditional creation of AV fistulas and is designed to be used by a physician under local or regional anesthesia in all sites of service including hospital outpatient departments, ambulatory surgical centers and physician offices.

Ultrasound is used to guide the Ellipsys catheter through the skin to the pre-determined vascular target. The catheter delivers a small amount of thermal energy that fuses a sutureless and permanent anastomosis, or connection, between the vein and artery allowing the creation of an AVF. Unlike surgery, the Ellipsys System uses a minimally invasive, endovascular approach that leaves the skin without a scar, and the vascular bed undisturbed and intact without leaving any foreign material implanted (including suture). After the procedure, the patient leaves with just a band aid.

Clearance was granted after the FDA reviewed data from a non-randomized, U.S. multi-center study of 103 patients. The study was designed to demonstrate the safety and efficacy of the Ellipsys System for the percutaneous creation of an AV fistula.

"This approval marks a seismic shift for the patients and physicians within the ESRD community. We can now offer a faster, more efficient and less-invasive option for patients requiring vascular access here in the US and worldwide" said Mark Ritchart, President of Avenu Medical. "For too long there has been a shortage of dedicated vascular surgeons who can create AV fistulas leading to delays in performing the surgery and requiring expensive, temporary catheter access. Our Ellipsys System has the potential to significantly increase the number of clinicians performing vascular access procedures, thereby reducing these delays. This, in turn, will result in reduced morbidity and the cost associated with temporary catheter access. In short, it represents a quality of life improvement opportunity for this patient community."

"Using the Ellipsys Vascular Access System is very similar to common procedures such as obtaining venous and arterial access with ultrasound," said Jeffrey E. Hull, MD, Director of the Richmond Vascular Center in Richmond, VA. "Most physicians involved in vascular access have the endovascular skills required and will learn to use the Ellipsys System quickly."

About ESRD

Today, more than two million ESRD patients worldwide receive hemodialysis therapy and require vascular access. In the U.S., more than 661,000 Americans have kidney failure, of which approximately two-thirds are on hemodialysis, and these numbers continue to grow. Clinical factors that are fueling these projections include the worldwide alarming rates of diabetes, hypertension and obesity. Almost 80% of the patients in the US start dialysis with a catheter, which has an extremely high infection rate along with significantly higher mortality rate when compared with a fistula.

About Avenu Medical

Avenu Medical, Inc. was founded in 2010 to pursue unmet clinical needs in the ESRD and vascular access market. The company has developed the Ellipsys Vascular Access System which is an innovative, ultrasound-guided, single catheter endoAVF system used to percutaneously create an arteriovenous (AV) fistula for hemodialysis access. Learn more at www.avenumedical.com.

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