For Immediate Release

Avenu Medical Receives CE Mark Approval for the Ellipsys® Vascular Access System

Company also completes full patient enrollment for pivotal Phase III clinical trial in the United States

San Juan Capistrano, CA, USA – June 1, 2016 – Avenu Medical, Inc. announced today that it has received CE Mark approval for the commercial sale of its Ellipsys® Vascular Access System, an innovative, single catheter image-guided system designed to meet the 21st century needs of vascular access for hemodialysis. With this authorization, Avenu can now launch the technology at clinical centers of excellence throughout Europe.

A groundbreaking innovation for dialysis patients and clinicians, Avenu's Ellipsys is the first medical device to be approved for study under an Investigational Device Exemption (IDE) by the FDA for minimally invasive creation of arteriovenous (AV) fistulas. The current gold standard of surgical fistula creation was established in 1966 and has not been significantly advanced since its inception 50 years ago.

News of Avenu receiving the CE Mark also comes on the heels of the company reaching full patient enrollment in its FDA-authorized pivotal phase III IDE clinical trial. This multi-center study is designed to demonstrate the safety and efficacy for the percutaneous creation of AV fistulas. The Company intends to file for FDA market authorization later this year.

Dialysis patients require consistent, effective, reproducible, and permanent vascular access. Meanwhile, surgical AV fistulas fail 40-60% of the time, often take several months to achieve usability and require multiple interventions to maintain functionality. In addition, patients often wait five months or longer to get a functioning surgical AV fistula. These factors result in the patients' extended exposure to central venous catheters, which can lead to increased risks for infection and mortality. Avenu's Ellipsys System introduces a modern alternative. Thanks to this new technology, clinicians now have a less invasive alternative to the creation of AV fistulas.

"This is a major milestone both for our company and for the patients and physicians within the End Stage Renal Disease (ESRD) communities," said Mark Ritchart, President of Avenu Medical. "In the United States and around the world, there is a shortage of dedicated vascular access surgeons who can create AV

fistulas. Our Ellipsys System has the potential to increase the number of clinicians performing vascular access procedures which may improve patient care by reducing time from request for fistula to usable access for dialysis. This, in turn, reduces the morbidity associated with temporary catheter access. In short, it represents significant quality of life improvement opportunity for this patient community."

"The procedure is simple and elegant. All the patients' care from fistula creation through maturation is delivered in the office-based vascular center," said Jeffrey E. Hull, MD, Director of the Richmond Vascular Center in Richmond, VA. "Using the Ellipsys Vascular Access System is very similar to common procedures such as obtaining venous and arterial access with ultrasound. This new, minimally invasive procedure requires similar skills. Most physicians involved in vascular access have these skills and will learn to use the Ellipsys System quickly."

"At the end of the day, approvals such as the CE Mark are exciting because we know that Ellipsys – and the percutaneous AV fistula creation it enables – can transform vascular access for dialysis patients. The Ellipsys technique will provide substantially more patients with a working fistula, for both pre-dialysis patients and existing dialysis patients," added Ritchart.

###

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, image-guided single catheter system used to percutaneously create an arteriovenous (AV) fistula for hemodialysis access. The Ellipsys Vascular Access System is an investigational device and is limited by federal law to investigational use and is not for sale in the United States. Learn more at www.avenumedical.com.

Media Contact:
Paul Williams
310/569-0023
paul@medialinecommunications.com