Vascular Therapies

Vascular Therapies Announces Presentation of Phase 3 Clinical Trial Results at the American Society of Nephrology Meeting

- Sirogen™ Shows Encouraging AV Fistula Outcomes in Elderly End-Stage Renal Disease Patients -

CRESSKILL, N.J., November 4, 2021 - Vascular Therapies, a privately held biotechnology company is developing Sirogen™, a proprietary sirolimus formulation for intraoperative local drug delivery to reduce surgical stenosis in blood vessels. Today the company announced the presentation of clinical results from its Phase 3 clinical trial (ACCESS 1) during the Late Breaking Clinical Trials section of the American Association of Nephrology Annual Meeting. The results were presented by Maria DeVita, MD, Senior Nephrologist at Lenox Hill Hospital in New York and Medical Monitor for the study.

The ACCESS 1 study enrolled 243 patients with end stage renal disease ("ESRD") and chronic kidney disease ("CKD") from 20 U.S. sites, including 20 nephrologists and 26 surgeons. The study was designed to evaluate the safety and effectiveness of Sirogen™ to improve outcomes in patients undergoing the surgical creation of an arteriovenous fistula ("AVF") to provide vascular access for hemodialysis. The primary endpoint of fistula suitability for dialysis at 6 months was not achieved, however, in post-hoc subgroup analyses the ACCESS 1 study revealed important potential benefits for ESRD patients age 65 and older who required an AVF for dialysis, namely:

- Improved overall AVF maturation
- Improved forearm (radio-cephalic) AVF maturation
- Improved suitability for dialysis at 12-months
- Improved secondary patency

Maria DeVita, MD, Senior Nephrologist at Lenox Hill Hospital in New York and Medical Monitor for the study commented, "The clinical results from the ACCESS 1 study are very encouraging, especially for ESRD patients age 65 and older, who represent 50% of the hemodialysis population in the U.S. Additionally, there were no unexpected adverse events, confirming the overall favorable safety profile of the product."

Sriram Iyer, MD, Chief Scientific Officer of Vascular Therapies added, "The findings from the ACCESS study address an important unmet need for elderly dialysis patients. We would like to thank the nephrologists, surgeons, clinical coordinators and patients for their participation in

the study."

John McDermott, Chief Executive Officer of Vascular Therapies commented, "We are pleased with several positive clinical findings from the ACCESS 1 study and have collaborated with the FDA to design ACCESS 2, a new clinical trial to validate the sub-group analysis from ACCESS 1. We are currently raising capital to fund ACCESS 2 and plan to start enrollment in the second quarter of 2022. I'd like to thank our investors for their support, and the talented team at Vascular Therapies for their efforts and dedication to develop Sirogen™ for patients requiring hemodialysis."

About Chronic Kidney Disease, Hemodialysis and Vascular Access

Chronic kidney disease (CKD), reduces a person's ability to effectively filter blood, causing wastes to build up in the body. Advanced CKD can progress to kidney failure, often referred to as end-stage renal disease (ESRD), which requires dialysis or transplantation to survive. The majority of ESRD patients undergo chronic hemodialysis, which requires functioning vascular access to connect the patient's bloodstream to a hemodialysis machine three times a week for this life-saving treatment. The preferred form of vascular access for hemodialysis is an arteriovenous fistula, created by connecting a vein to an artery.

About Vascular Therapies (www.vasculartx.com):

Vascular Therapies, Inc. ("VT") is a privatelyheld, biotechnology company that has developed Sirogen™, a proprietary sirolimus formulation for local, perivascular drug delivery to reduce surgical stenosis in blood vessels. The goal of this therapeutic approach is to improve vascular surgery outcomes in patients with kidney and vascular diseases. The Sirogen™ development program has received Fast Track status from the FDA and sirolimus has Orphan Drug designation for dialysis vascular access indications in the U.S. and E.U. FDA has tentatively approved the proprietary tradename Sirogen™ for VT's formulation of sirolimus for intraoperative use. Sirogen™ is an investigational product and has not been determined by the FDA to be safe and effective for any use.

Company Contact

John McDermott
Chief Executive Officer
Vascular Therapies, Inc
jmcdermott@vasculartx.com