Vascular Therapies

Vascular Therapies Completes Enrollment in the ACCESS Study, a U.S. Phase III Clinical Trial

Trial will evaluate the effectiveness of perivascular sirolimus to improve AV Fistula outcomes in patients with kidney disease

CRESSKILL, N.J., August 19, 2019 /PRNewswire/ -- Vascular Therapies, a biotechnology company focused on improving vascular access outcomes in patients with kidney disease, today announced completion of enrollment in its US Phase III prospective randomized, multicenter, clinical study (ACCESS Trial).

The company is developing a proprietary sirolimus formulation for intraoperative local, perivascular drug delivery. The ACCESS Study was designed to evaluate the effectiveness of the sirolimus drug product to improve outcomes in patients undergoing surgical creation of an arteriovenous fistula ("AV fistula") to provide vascular access for hemodialysis. This multicenter randomized study enrolled 269 patients across 20 centers in the United States. The Phase 3 trial design included an open label subset – the first patient enrolled by a surgeon, definitely received the sirolimus drug product. The primary endpoint of the study is Fistula Suitability for Dialysis at 6 months and results are expected to be announced in the second quarter of 2020.

John McDermott, CEO of Vascular Therapies said "We are very pleased to complete enrollment in this important clinical study. Although AV fistula is the preferred vascular access for most hemodialysis patients, there is still an unacceptably high rate of failure that can lead to complications, reinterventions and increased costs. We look forward to gathering the clinical results from the ACCESS Study over the coming months and hope to provide patients with kidney disease and their physicians a new therapy to improve outcomes and lower costs in the future." Sriram Iyer, MD, Chief Scientific Officer of Vascular Therapies added "The encouraging outcomes of the open label subset indicates potential to bridge an important unmet clinical need. We would like to thank the patients, nephrologists, surgeons and clinical coordinators and are very grateful for their participation in this study."

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 a 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 privately-held, biotechnology company that has developed a proprietary sirolimus formulation for local, perivascular drug delivery. The goal of this therapeutic approach is to improve vascular surgery outcomes in patients with kidney and vascular diseases. This investigational therapy is currently being evaluated in a Phase III randomized clinical trial which is being performed under a Special Protocol Assessment (SPA). The drug development program has received Fast Track status from the FDA and sirolimus has Orphan Drug designation for the dialysis vascular access indications in the U.S. and E.U.

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