Vascular Therapies

Vascular Therapies Announces Positive Preliminary Clinical Results from its AV Fistula Trials in Patients with Kidney Disease

CRESSKILL, N.J., September 5, 2019 /PRNewswire/ -- Vascular Therapies, a clinical stage biotechnology company, is developing Sirogen™, a proprietary sirolimus formulation for intraoperative local, perivascular drug delivery focused on improving vascular access outcomes in patients with kidney disease. Daniel G. Clair, MD, vascular surgeon and Chairman of the Department of Surgery at Palmetto Health-USC Medical Group in Columbia, South Carolina presented preliminary results from the company's clinical development program at the recent Eastern Vascular Society Meeting in Pittsburg, Pennsylvania.

The presentation included outcomes of two cohorts - a non-randomized Phase 2 (n=30; 2 international sites, 2 surgeons) and the open label subset (OL; n=26; 20 U.S. sites, 26 surgeons) of the ACCESS study, an ongoing, randomized, controlled, multicenter US Phase 3 trial. For the composite study group of 56 patients:

- 78% and 73% of AVF were suitable for dialysis at 6 and 12 months respectively
- Median time to first dialysis was 49 days
- 12-month secondary patency was 73%
- No product related serious adverse events were reported

These outcomes provide a strong efficacy signal. Enrollment in the ACCESS study was completed in August 2019 and included 243 patients. The 6-month primary endpoint (Fistula Suitability for Dialysis at 6 Months) results are expected to be announced in the second quarter of 2020.

Dr. Clair commented "these preliminary results are very encouraging and suggest that intraoperative perivascular sirolimus may improve AV fistula outcomes in dialysis patients. We look forward to seeing the primary endpoint results from the randomized cohort." Maria DeVita, MD, Chief of Nephrology at Lenox Hill Hospital in New York and medical monitor for the study added "Vascular access failures in hemodialysis patients is an important unmet medical need. I commend Vascular Therapies for developing this therapy and would like to thank the patients, nephrologists, surgeons and clinical coordinators for their participation in these important studies."

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 Sirogen™, 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. 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.

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