Mercator MedSystems Announces Publication of Results from TANGO Phase 2 Clinical Trial to Improve Outcomes after Below-Knee Arterial Revascularization

First U.S. Double-Blinded Randomized Controlled Trial to Date Addressing Unmet Needs in Critical Limb Ischemia

SAN LEANDRO, CA / ACCESSWIRE / November 3, 2022 / Mercator MedSystems, Inc. ("Mercator"), a medical technology company specializing in local drug delivery, announced today that their data from the TANGO (Temsirolimus adventitial delivery to improve ANGiographic Outcomes below the knee) Phase 2 trial has been published in the Journal of Endovascular Therapy (https://doi.org/10.1177/15266028221131459). The trial examined the local delivery of a rapamycin analog (temsirolimus) to tissues around arteries with the intent to reduce the symptomatic re-obstruction of atherosclerotic arteries below the knee after catheter procedures were used to open the vessels and restore blood flow to the foot. The drug was delivered by Mercator's Bullfrog Micro-Infusion Device, an FDA-cleared product with a sheathed microscopic needle design that, upon inflation of a balloon at the tip of the device, slides the microneedle through the blood vessel wall to deposit drug into the adventitia, a biologically rich tissue where active cells are known to propagate during the vessel scarring process.

In patients with atherosclerosis of the lower leg, catheter-based procedures to restore blood flow typically involve balloon angioplasty, which opens the artery by displacing obstructions using a high-pressure balloon, or atherectomy, which physically alters the obstructions by laser, micro-cutters, or micro-sanding surfaces. However, around half of these treatment results are not durable, with a return of pain or other symptoms due to re-obstruction within 6 months of the mechanical intervention. Interventional procedural durability remains a large unmet need in critical limb ischemia and particularly for below-the-knee interventions.

The outcomes from the TANGO clinical trial were positive, as measured by clinically relevant target lesion failure, a composite of symptomatic re-obstruction or need for an additional procedure to reopen the artery within the first 6 months after the initial procedure. This failure rate was reduced by a relative 51.3% between trial participants receiving a placebo sham injection and those receiving the active drug. A measurement of the area of open artery when viewed from the side by X-ray also demonstrated beneficial trends at 6 months after the initial procedure, in which the amount of arterial side-view area lost in the first 6 months was 37.3% less, relatively, in treatment patients versus controls. Importantly, this was the first trial of a local drug therapy for the small below-the-knee arteries in the U.S. to report dual-blinded, randomized, controlled positive data. The use of dual blinding in clinical trials is important to remove inherent bias in analyzing patient outcomes and is used to increase the robustness of clinical signals.

Ken Ouriel, MD, MBA, the corresponding author for the manuscript and Chief Medical Officer at NAMSA/Syntactx, noted, "The TANGO trial represents important Level 1 evidence supporting the efficacy of drug delivery into stenotic and occluded arteries - lesions that have historically been difficult to treat and maintain long-term patency. The efficiency with which the drug was delivered into the vessel wall in this study is a likely contributor to the greater success observed in comparison to other technologies. I am excited to see this technology continue through subsequent trials towards potential regulatory approval."

The TANGO study was designed and funded by Mercator, with additional funding from grants issued by the National Institutes of Health's National Heart, Lung, and Blood Institute. Kirk Seward, PhD, the President and Chief Science and Technology Officer of Mercator and the NIH grant's principal investigator, added, "Publication of this data is an important milestone for Mercator as we continue our pursuit to optimize strategies for treating patients with debilitating pain and ischemia in their legs. As we advance this program into a Phase 3 trial and seek FDA approvals, we have the positive data to inform our decisions and guide our research design. We look forward to the potential ability to help many more patients down the road."

Research reported in the publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number R44HL102998. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

About the Bullfrog® Micro-Infusion Device

The Bullfrog Micro-Infusion Device is FDA cleared and CE marked. The device includes a balloon that hydraulically deploys a micro-needle through the vessel wall into perivascular tissues, where the needle can then efficiently infuse drugs or biologics around an artery or vein. Drug delivery through the Bullfrog is tracked with X-ray contrast agents, allowing precision therapy to local tissues with visual feedback to the physician using the device.

About Mercator MedSystems, Inc.

Mercator is a medical technology company focused on the clinical and commercial development of proprietary, FDA-cleared and CE marked catheter-based micro-infusion technologies, including the Bullfrog® Micro-Infusion Device for the local delivery of therapeutics in blood vessels and the Blowfish® Transbronchial Micro-Infusion Catheter for delivery in airways. Mercator is developing clinical applications in peripheral vascular disease, cancer, hypertension and cardiac regeneration. For further information, please visit www.mercatormed.com.

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