

Mercator MedSystems Initiates U.S. Study to Evaluate Use of Dexamethasone to Treat Peripheral Artery Disease

300 Patient National Study to Show Effectiveness of Adventitial Therapy

SAN LEANDRO, Calif., November 6, 2013 — Mercator MedSystems, a venture-backed, privately held medical technology company delivering customizable solutions for significant diseases, today announced the enrollment of the first patient in the company's prospective, 300 patient, 30 U.S. site DANCE (*Dexamethasone to the Adventitia to eNhance Clinical Efficacy*) clinical trial to study a new therapeutic approach to treating peripheral artery disease (PAD). In the DANCE trial, the procedure incorporates the use of Mercator MedSystems' FDA-cleared Micro-Infusion drug delivery system.

PAD, which has become a very serious global health problem, occurs when fatty deposits collect in the peripheral arteries, restricting blood flow and oxygen to the legs and feet. Restricted blood flow results in difficulty with walking, an increased risk of heart attack or stroke, or amputation. New worldwide estimates published in *The Lancet* estimate the number of people suffering with PAD to be 202 million in 2010 – including 17 million Americans.

The DANCE trial is being performed to corroborate results coming from the 20-patient DANCE Pilot, which was performed by Chris Owens, MD, MSc, at the San Francisco VA Medical Center in California. The primary objective of the DANCE trial is to assess the reduction of inflammation and restenosis in patients with PAD by delivering dexamethasone, an anti-inflammatory steroid, to the *adventitia* – or outer tissue layer of a blood vessel. National co-principal investigators are Chris Owens, MD, MSc, University of California, San Francisco, and Mahmood Razavi, MD, of St. Joseph Hospital Heart and Vascular Center in Orange, CA. The first procedure was performed by Stuart Harlin, MD, FACS, at the Coastal Vascular and Interventional Center, in Pensacola, FL.

Mercator is attempting to improve the treatment of PAD by allowing clinicians to accurately and efficiently deliver small volumes of anti-inflammatory drug to the adventitia, which becomes highly inflamed during procedures to open the artery. "Until now, doctors have had to rely on indirect, non-specific methods of controlling inflammation from the inside of the blood vessel. We believe the 'outside-in' approach will potentially better target the localized injury caused by vascular procedures such as balloon angioplasty or atherectomy," explained Mercator Chief Executive Officer Thomas M. Loarie.

Immediately following the first procedure, Dr. Harlin said he believes Mercator's Micro-Infusion Device returns therapeutic freedom back to the physician. "We believe we now have the ability to deliver *what* is needed precisely *where* it is needed in the body," he said. "There are no guessing games – we can *see and feel* the drug being delivered."

About Mercator MedSystems, Inc.

San Leandro, CA-based Mercator MedSystems, Inc. (www.mercatormed.com) is a venture-backed, privately held medical technology company delivering innovative, customizable, treatment solutions for intractable problems associated with some of the world's most significant diseases. The company develops catheter-guided micro-infusion systems for targeted delivery of drugs and biologics deep inside the body to treat the root cause of a growing portfolio of medical conditions, including cardiovascular disease, cancer, hypertension and heart disease.