

Singapore-developed Drug Coated Chocolate® Balloon Enrols its First Patients in Clinical Study

Second Generation drug coated balloon designed to address both acute and long-term outcomes

SINGAPORE, March 27, 2014 -- TriReme Medical LLC, a subsidiary of Singapore-based QT Vascular Ltd. announced today that three patients have been enrolled in a clinical study of its unique drug-coated Chocolate® PTA balloon. Dr. Andrew Holden, co-Principal Investigator of the study, performed these procedures at Auckland City Hospital, in Auckland, New Zealand.

The drug-coated Chocolate® PTA balloon, developed and manufactured in Singapore, is designed for the treatment of patients with vascular disease in their legs, known as peripheral arterial disease (PAD). The drug-coated Chocolate® PTA balloon is unique in that it combines the acute benefits of the FDA and CE approved Chocolate® PTA balloon with paclitaxel-based coating, an anti-proliferative drug proven to reduce the build-up of tissue in the vessel that can occur months after the original procedure. The underlying Chocolate® PTA balloon platform has demonstrated a very low rate of dissections and bail out stenting in clinical studies (1).

A previous iteration of the device, the Chocolate® PTA Balloon Catheter, was the first Singapore-developed interventional device to receive FDA Approval. This was achieved in a record time of less than two years.

The drug-coated Chocolate® clinical study is a single arm trial that will enroll a minimum of 30 patients at up to four centers in New Zealand and Germany. The trial will evaluate the rate of procedural success immediately after treatment as well as persistence of positive outcomes at 6 and 12 months post procedure. All key outcomes of the trial will be evaluated by independent core laboratories.

"The first three complex cases in this study highlight the advantages of the underlying Chocolate® platform in creating a larger and more uniform lumen while minimizing vessel trauma," stated Dr. Andrew Holden, Director of Interventional Services at Auckland City Hospital and Associate Professor of Radiology at Auckland University School of Medicine.

"First Generation drug-coated balloons are based on Plain Old Balloon Angioplasty (POBA) technology that goes back more than 30 years. POBA is well known to induce significant vessel trauma and often requires adjunctive stenting to complete the procedure," added Dr. Eitan Konstantino, President and CEO, TriReme Medical. "The mere addition of a drug does not solve this issue. The drug coated Chocolate® PTA balloon is the only product that is designed to address both the acute trauma and long term results."

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About Peripheral Arterial Disease

Peripheral artery disease (PAD) is caused by the build-up of fatty substances that collect and adhere to the linings of the arteries, in a process known as atherosclerosis. The build-up causes the internal lining of the artery to thicken, narrowing the artery and limiting blood



flow to vital tissues and organs. Commonly affected arteries include those located in the legs, arms, neck and kidneys. The vast majority of patients with PAD also have significant concomitant coronary artery disease (CAD) and a high proportion of morbidity and mortality in these patients is related to myocardial infarction, ischemic stroke or cardiovascular death. PAD is estimated to affect 202 million people worldwide (2).

About TriReme Medical, LLC

TriReme, a subsidiary of Singapore based QT Vascular Ltd., is an emerging leader in the development and commercialization of next generation minimally invasive devices for the treatment of complex arterial disease. The company is focused on the US and the emerging Asian markets.

- (1) Das T for Mustapha J. Chocolate® Bar, Leipzig Interventional Course, 28-31 January, 2014.
- (2) "Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis." 19 Oct 2013. The Lancet.

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