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TriReme enrols patients for drug-coated Chocolate PTA balloon

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Singapore: TriReme Medical, a subsidiary of Singapore-based QT Vascular, has enrolled three patients in a clinical study of its 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 combines 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.

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."