



MEDIA RELEASE

QT VASCULAR SUBMITS IDE REQUESTING PERMISSION TO BEGIN PIVOTAL TRIAL OF ITS DRUG-COATED CHOCOLATE BALLOON IN THE UNITED STATES

Highlights:

- Chocolate Touch™ is the first 2nd generation drug-coated balloon, designed to optimize both acute and long-term outcomes
- Design of the pivotal study features first head-to-head randomization against another drug-coated balloon
- The submission summarizes years of development and is a significant step in the US regulatory path

SINGAPORE, 25 April 2016 – QT Vascular Ltd. (the “**Company**” or “**QT Vascular**”, and together with its subsidiaries, the “**Group**”), a global company engaged in the design, assembly and distribution of advanced therapeutic solutions for the minimally invasive treatment of vascular disease, announced today it has submitted an investigational device exemption (“**IDE**”) for permission to begin the pivotal study of Chocolate Touch™, its drug-coated balloon, in the United States (“**US**”).

Chocolate Touch™ is the drug-coated version of the Company’s Chocolate® PTA balloon. Chocolate® PTA features a unique nitinol constraining structure that causes the balloon to open in a controlled uniform fashion, thus reducing acute trauma, dissections, and unplanned stenting compared to conventional PTA balloons¹. To complement these beneficial acute outcomes, the Company has added a proprietary coating of the drug, paclitaxel, to the Chocolate® platform in order to reduce the incidence of repeat procedures. This combination of an atraumatic balloon platform and a proven therapeutic agent is intended to allow patients to be treated without the need for a permanent implant such as a metallic stent.

“The Chocolate Touch™ pivotal study is the first of its kind to randomize against an existing drug coated balloon, the Lutonix device from CR Bard”, stated Dr. Mehdi Shishehbor of the Cleveland Clinic, co-Principal Investigator. “This state-of-the-art trial design combined with a next generation device is designed to provide physicians and patients the ability to compare treatment options and their performance.”

The Chocolate Touch™ proposed US pivotal study is a prospective randomized study in the United States, Europe, and New Zealand that will evaluate patients with symptomatic, *de novo* disease in the superficial femoral and popliteal arteries. Patients will be randomized 1:1 to the Lutonix drug-coated balloon. The study will evaluate acute end points such as procedural successes and freedom from bail-out stenting, and long term endpoints such as patency, and target lesion revascularization.

“This IDE submission is the culmination of years of careful product development, bench tests, pre-clinical experiments and clinical studies,” stated Dr Eitan Konstantino, PhD, CEO of QT Vascular. “This is a significant step for the Company on our path toward being one of the few players in the United States’ rapidly growing market for drug-coated balloons.”

Drug-coated PTA balloons represent a new category of device that combines the mechanical dilatation of a balloon catheter with the biological effect of a drug to treat occluded arteries. These devices have been available for several years in Europe and were recently approved in the US. Since their approval in the US, adoption has been increasing and CMS (Centers for Medicare and Medicaid Services) has granted additional reimbursement for these devices. According to some analyst estimates², revenues for drug-coated balloons are expected to reach US\$1 billion by 2020.

The Company’s Chocolate Touch™ received CE mark approval in July 2015. The Company has previously announced strong acute and 6 month outcomes in its feasibility study for Chocolate Touch™, ENDURE, with an incidence of bail-out stenting just 1.4%, a lumen loss of only 0.16mm, per-protocol primary patency of 90% and an incidence of clinically-driven target lesion revascularization of only 1.7%. Commercial launch of Chocolate Touch™ in selected countries that are accepting CE mark is underway. The product is not yet approved for use in the US and the receipt of CE mark does not constitute such approval.

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1. Chocolate BAR interim results presented by Mustapha (AMP, August 2015)
2. Morningstar (July 30, 2015)

ABOUT QT VASCULAR LTD. (SGX Stock code: 510)

QT Vascular Ltd. together with its subsidiaries (“**QT Vascular**” or the “**Group**”), is an emerging leader in the development and commercialization of next generation minimally invasive products for the treatment of complex vascular disease. QT Vascular works closely with leading physicians and scientists from around the world to create differentiated devices that improve procedural and clinical outcomes.

QT Vascular is based in Singapore with a US subsidiary, TriReme Medical LLC (“**TriReme Medical**”), based in Pleasanton, California. TriReme Medical’s range of percutaneous transluminal angioplasty (“**PTA**”) and percutaneous transluminal coronary angioplasty (“**PTCA**”) products include (i) Chocolate® PTA Balloon Catheter, (ii) Chocolate® PTCA Balloon Catheter, (iii) GliderXtreme™ PTA Balloon Catheter, (iv) GliderfleX® PTA Balloon Catheter and (v) Glider™ PTCA Balloon Catheter, all of which have the CE Mark that allows them to be sold in Europe, and FDA clearance to be sold in the United States. Additionally, the GliderXtreme™ PTA Balloon Catheter has the regulatory clearance in China and Japan, while the Glider™ PTCA Balloon Catheter has the regulatory clearance in Japan. These products are sold through its main distributors: (i) Cordis Corporation (a wholly-owned subsidiary of Cardinal Health, Inc.), (ii) Shandong Weigao Group Medical Polymer Co Ltd and (iii) Century Medical, Inc.

For more information, please visit the company website at www.qtvvascular.com

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QT Vascular Ltd. (the “Company”) was listed on Catalist board of the Singapore Exchange Securities Trading Limited (the “SGX-ST”) on 29 April 2014. The initial public offering of the Company was sponsored by PrimePartners Corporate Finance Pte. Ltd. (the “Sponsor”).

This press release has been prepared by the Company and its contents have been reviewed by the Sponsor for compliance with the SGX-ST Listing Manual Section B: Rules of Catalist. The Sponsor has not verified the contents of this press release.

This press release has not been examined or approved by the SGX-ST. The Sponsor and the SGX-ST assume no responsibility for the contents of this press release including the accuracy, completeness or correctness of any of the information, statements or opinions made or reports contained in this press release.

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