QT Vascular Receives CE Mark Clearance For Chocolate Heart™, A Novel Drug-Coated Coronary Balloon

Highlights:

- Chocolate Heart™ drug-coated PTCA balloon approved for use in coronary interventions
- Chocolate Heart™ may offer a new paradigm for the treatment of certain patients with coronary artery disease
- First-in-Human ("FIH") study of Chocolate Heart™ showed excellent results in-hospital, at 30 days, and at 6 months

SINGAPORE, July 7, 2016 /PRNewswire/ -- QT Vascular Ltd., together with its subsidiaries (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 received CE mark clearance for the sale and distribution of the Chocolate Heart™ drug-coated PTCA balloon for dilatation of the stenotic portion of coronary arteries for the purpose of improving myocardial perfusion in Europe.

Chocolate Heart™ is the drug-coated version of the Company's Chocolate® PTCA balloon that has been commercially available in the United States ("**US**") since late 2014. Chocolate® PTCA features a unique nitinol constraining structure that causes the balloon to open in a controlled uniform fashion, thus is designed to reduce acute trauma, dissections, and unplanned stenting compared to conventional balloons. Initial evidence of this has previously been demonstrated in a trial of the peripheral version of Chocolate® known as Chocolate® PTA ("**Chocolate BAR**")[1]. The Company has added a proprietary coating containing the proven drug, paclitaxel, to the Chocolate® PTCA 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 certain patients to be treated with Chocolate Heart™ while avoiding the need for a permanent implant such as a metallic stent.

The FIH study of Chocolate Heart™ was conducted at CECANOT Hospital in Santo Domingo, Dominican Republic in 19 patients with *de novo* coronary lesions. The results of this novel study were recently presented by the IVUS core lab principal investigator, Dr. Alexandre Abizaid of Dante Pazzanese Hospital in Sao Paolo, Brazil. In-hospital and after 30 days, the incidence of acute closure was 0% compared to over 9%[2] for conventional balloon angioplasty. At 6 months, the late lumen loss was only 0.01mm with a rate of target lesion re-treatment of only 5%. **"**For a small first-in-human study, these

results are very promising,**"** stated Dr. Abizaid. "The late lumen loss is much lower compared to conventional balloon therapies, including stents. I'm looking forward to additional larger studies that may confirm the benefit of this exciting new treatment option for patients suffering from coronary artery disease."

Drug-coated balloons represent a rapidly growing new category of device that combines the mechanical dilatation of a balloon catheter with the biological effect of a drug to treat occluded arteries in the leg. These devices have been available for several years in Europe and were recently approved in the United States. Since their approval in the U.S., adoption has been increasing and CMS (Centers for Medicare and Medicaid Services) has granted additional reimbursement for these devices. According to some analyst estimates[3], revenues for drug-coated peripheral balloons are expected to reach $1 billion by 2020. The Company believes that drug-coated balloons may also play an important role in the future in the treatment of patients with disease in their coronary arteries.

"We are delighted with the CE mark clearance of our novel Chocolate Heart™ drug-coated PTCA balloon," stated Eitan Konstantino, PhD, CEO of QT Vascular. "The opportunity to minimize the use of metallic stents is greater in the coronary compared to any other arteries. We intend to increase our focus on the coronary business and build evidence to help improve patients care."

QT Vascular is developing drug-coated balloons for the treatment of both peripheral and coronary artery disease. Its Chocolate Touch® drug-coated PTA balloon 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 approved for use in the US and CE mark does not constitute such approval.

1. Chocolate BAR interim results presented by J. Mustapha, MD (AMP, August 2015)
2. BARI investigators, NEJM, July 25, 1996
3. Morningstar (July 30, 2015)

About QT Vascular Ltd. (SGX Stock code: 5I0)

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 by the Group's direct sales team and 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.

The Group's drug coated version of the Chocolate® PTA Balloon Catheter, Chocolate Touch®, and the Chocolate® PTCA Balloon Catheter, Chocolate Heart™, have the CE mark that allows them to be sold in Europe.

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