QTVascular

MEDIA RELEASE

QT VASCULAR ANNOUNCES FDA HAS GRANTED APPROVAL TO INITIATE THE PIVOTAL TRIAL OF ITS NOVEL DRUG-COATED BALLOON

Highlights:

- **Chocolate Touch™ is the first 2nd generation drug-coated balloon, designed to optimize both acute and long-term outcomes**
- **Conditional IDE approval allows the Company to begin clinical study that is the next critical step in the US regulatory path**
- **Design of the pivotal study features first head-to-head randomization against another drug-coated balloon**

SINGAPORE, 19 September 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 that the Food and Drug Administration ("**FDA**") has granted it conditional Investigational Device Exemption ("**IDE**") approval. This approval allows the Company to begin enrolling patients in the pivotal study of its novel Chocolate Touch™ drug-coated balloon. The approval follows an extensive review by FDA of the Chocolate Touch™ technology including pre-clinical data, drug coating, bio safety, design features and clinical data.

"Currently, available drug-coated balloons provide better patency compared to uncoated balloons. However, they are all based on Plain Old Balloon Angioplasty (POBA) platforms which induce acute arterial trauma and dissection. The Chocolate Touch™ is a second generation drug-coated balloon using an advanced platform that may allow patients to be treated while minimizing the need for stents**"**, stated Dr. Mehdi Shishehbor of the Cleveland Clinic, co-Principal Investigator. "Previous studies[1,2] showed the potential of this product at improving both acute and long-term outcomes. Now these promising earlier results will be studied in a much larger and more tightly controlled clinical trial setting."

The Chocolate Touch™ US pivotal study is a prospective randomized study in the United States ("**US**"), Europe, and New Zealand that will evaluate patients with disease in the superficial femoral and popliteal arteries in the legs. Patients will be randomized 1:1 to CR Bard's 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 among others.

“We are thrilled to receive this conditional IDE approval from FDA,” stated Eitan Konstantino, PhD, CEO of QT Vascular. “This approval concludes a highly sophisticated research effort and marks a significant step towards joining the exclusive list of companies able to sell drug-coated balloons in the 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 balloons[1]. To complement these excellent acute outcomes, the Company has added a proprietary drug coating containing 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 while minimizing the need for a permanent implant.

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 to create a second generation of drug-coated balloons. 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 estimates[3], revenues for drug-coated balloons are expected to reach $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 approved for use in the US and CE mark does not constitute such approval.

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1. Chocolate BAR interim results presented by Mustapha (AMP, August 2015)
2. ENDURE interim results presented by Zeller (German Society of Angiology, September 2015)
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

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