



MEDIA RELEASE

FDA GRANTS QT VASCULAR FULL IDE APPROVAL TO BEGIN PIVOTAL TRIAL OF ITS DRUG-COATED BALLOON, CHOCOLATE TOUCH™

Highlights:

- **QT Vascular met all FDA requirements for safety and received a full IDE approval**
- **QT Vascular plans to begin patient enrollment early next year in the United States, Europe and New Zealand**
- **This is an important milestone that demonstrates the continued success and high quality of the program**

SINGAPORE, 16 December 2016 – QT Vascular Ltd., (the “**Company**” or “**QT Vascular**”, and together with its subsidiaries, the “**Group**”), is a global company engaged in the design, assembly and distribution of advanced therapeutic solutions for the minimally invasive treatment of vascular disease. Further to the Company’s announcement on 19 September 2016 in relation to the Food and Drug Administration (“**FDA**”)’s grant of conditional Investigational Device Exemption (“**IDE**”) approval, the Company is pleased to announce that the FDA has granted the *full* IDE approval to begin enrolling patients in the pivotal study of its novel Chocolate Touch™ drug-coated balloon. The full IDE approval allows for enrollment up to 585 patients and up to 50 centers in the United States (“**US**”) while additional patients may be enrolled in selected centers outside the US. The co-Principal Investigators of the study are Dr. Mehdi Shishehbor of the Cleveland Clinic and Professor Thomas Zeller of the Heart Center in Bad Krozingen, Germany.

“FDA appropriately set a high bar for this type of drug device combination product” stated Eitan Konstantino, PhD, CEO of QT Vascular. “We have worked hard to meet all conditions previously set by the FDA and are delighted to join a very small group of companies able to reach this point with a drug-coated balloon”.

The Chocolate Touch™ US pivotal study is a prospective randomized study in the 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.

Chocolate Touch™ is the drug-coated version of the Company's Chocolate® PTA balloon which is already broadly available in hospitals across the United States. 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. For Chocolate Touch, 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.

Chocolate Touch™ received CE mark approval in July 2015. Commercial launch in selected accounts in countries that are accepting CE mark is underway. 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%. The product is not approved for use in the US and CE mark does not constitute such approval.

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. Since their approval in the United States, adoption has been increasing and CMS (Centers for Medicare and Medicaid Services) has granted additional reimbursement for these devices. According to some analyst estimates³, revenues for drug-coated balloons are expected to reach \$1 billion by 2020.

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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: 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 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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*This press release has been prepared by the Company and its contents have been reviewed by the Company’s sponsor, PrimePartners Corporate Finance Pte. Ltd. (“**Sponsor**”), for compliance with the Singapore Exchange Securities Trading Limited (“**SGX-ST**”) Listing Manual Section B: Rules of Catalist. The Sponsor has not verified the contents of this press release.*

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