# QT VASCULAR BEGINS ENROLLMENT IN US PIVOTAL STUDY OF ITS DRUG-COATED PERIPHERAL BALLOON

**SINGAPORE, 31 July 2017 –** QT Vascular Ltd., together with its subsidiaries (**the "Company"**), announced it has started enrollment in its United States ("**US**") pivotal clinical study. The study will evaluate the Company's drug coated balloon ("**DCB**"), the Chocolate Touch®, for use in superficial femoral and popliteal arteries with the intention of obtaining a US regulatory approval. The co-principal investigators of the study are Dr. Mehdi Shishehbor of the University Hospitals of Cleveland and Professor Thomas Zeller of the Heart Center in Bad Krozingen, Germany.

The clinical trial is a first of its kind, randomized study comparing two DCBs. The main objective of the study is to demonstrate non-inferior safety and effectiveness of the Chocolate Touch® compared to the Lutonix® DCB catheter from C.R. Bard, Inc. (NYSE:BCR). The study is also designed to further evaluate superiority of Chocolate Touch® over Lutonix® DCB. Enrollment will include 510 randomized patients, with an interim analysis after 75% of the patients completed 12-month follow-up. This analysis can potentially support earlier submission of the results. The primary effectiveness endpoint is "true DCB success", a composite result requiring patients to achieve primary patency in the absence of bailout stenting.

"I'm delighted to start enrollment in this important study," said Professor Zeller. "We believe that the unique properties of Chocolate®, namely larger lumen with less dissections and bailout stenting, make this a differentiated DCB option. This head-to-head study against Lutonix® DCB is set up to demonstrate this point."

"We are excited about the first patient enrollment in this worldwide study evaluating Chocolate®, a second-generation DCB," said Dr. Shishehbor. "This first of a kind trial will help guide physicians as they choose the best DCB for their patients."

The Company's 12-month outcomes in Chocolate Touch® ENDURE study showed an incidence of bailout stenting of just 1.4%. The primary patency rate was 83.6% and the Kaplan Meier patency was 89.9%.

"DCBs are demonstrating significant US sales despite limitations and lack of differentiation," said Eitan Konstantino, PhD, CEO of QT Vascular. "The Chocolate® platform is different and we are encouraged by the clinical results to date."

The product is not approved for use in the US and the receipt of the CE mark approval in July 2015 does not constitute such approval.

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**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.

For more information, please visit the Company's website at www.qtvascular.com

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