

TriReme Medical Reports Results from Clinical Trial of Chocolate® PTA Device at the 10th Annual Leipzig Interventional Course

Interim Outcomes in CHOCOLATE BAR Registry Demonstrate High Rates of Procedural Success and Limb Preservation

PLEASANTON Calif. and SINGAPORE, February 6, 2014 /PRNewswire/ -- Interim results from The CHOCOLATE® BAR Registry conducted in the US demonstrate that use of the Chocolate® PTA balloon achieved high rates of treatment success and limb preservation in patients with peripheral arterial disease. The results from the first 350 patients enrolled and treated were presented by Dr. Tony Das (Cardiovascular Research Institute, Dallas, TX) at the Leipzig Interventional Course, LINC 2014.

CHOCOLATE® BAR is a prospective, core lab adjudicated registry conducted at 33 clinical centers in the US. A broad range of patients with advanced atherosclerotic disease in their legs were treated in this trial including patients with high risk of amputation (Rutherford 5 and 6, total occlusions, long and calcified lesions). The study included two distinct patient groups: those with atherosclerotic disease mainly in above-the-knee vessels (ATK) or below-the-knee vessels (BTK). Dr. Das reported the protocol mandated three month and six month follow up respectively.

The highlights of the interim data presented included:

- Treatment was completed without major dissection in 98% of all patients
- Affected limbs were preserved at follow up in 96% of ATK patients and 97% of BTK patients
- Re-intervention of the limb was not required in 89% of ATK patients and 93% of BTK patients

Dr. Jihad Mustapha (Metro Hospital, Wyoming, MI), Principal Investigator for the Trial, commented, "In this all-comers registry comprised of a large number of patients with diabetes and some of the most complex lesions including chronic total occlusions and high degrees of calcium, these results with Chocolate® are remarkable. Chocolate® is an attractive alternative to conventional therapies that often have poor outcomes."

"Chocolate® allows me the confidence to achieve a larger lumen without the concern that I might dissect the vessel and have to leave behind a permanent implant such as a stent," added Dr. Andrej Schmidt (Park Hospital, Leipzig, Germany) who successfully used Chocolate® during a live case transmission at the LINC 2014 conference.

"We are delighted with the outcomes presented," announced Dr. Eitan Konstantino, President and CEO of TriReme Medical. "This study enrolled patients with significantly more advanced disease than most other studies and yet our clinical outcomes are competitive with currently available advanced therapies, including first generation drug-coated balloons."

About TriReme Medical, LLC

TriReme, a subsidiary of Singapore based QT Vascular Ltd., is an emerging leader in the development and commercialization of next generation minimally invasive devices for the treatment of complex arterial disease. The company is focused on the US and the emerging Asian markets.