TriReme Medical, Inc. Receives FDA 510(K) Clearance for Chocolate PTA Balloon Catheter

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PLEASANTON, Calif., Dec. 21, 2011 /PRNewswire/ -- TriReme Medical, Inc. ("TriReme"), a leading developer of innovative devices for the treatment of complex vascular disease, announced today that it has received 510(K) clearance from the U.S. Food and Drug Administration to market its Chocolate PTA balloon catheter ("Chocolate") for the treatment of occluded peripheral arteries. Chocolate was developed in collaboration with TriReme's subsidiary, Quattro Vascular Pte Ltd in Singapore. Chocolate's novel design incorporates a constraining structure over a semi-compliant balloon to facilitate the formation of small modules ("pillows"). Through this advance mechanism of action, Chocolate minimizes shear stress and allows for uniform inflation and rapid deflation. The Chocolate "pillows" can expand locally to facilitate plaque modification and are designed to lower the strain and trauma induced on the vessel wall.

"I am very excited to be the first physician to use Chocolate PTA in the US," said Dr. Jihad Mustapha, Director of Endovascular Interventions and Research at Metro Health Hospital in Wyoming, Michigan. "We treated complex occlusions with outstanding results, no elastic recoil and no dissections which are the most feared complications in patients with Critical Limb Ischemia. This product will be a crucial tool in the battle against Critical Limb Ischemia and major amputations."

"We are pleased to receive US regulatory approval for Chocolate PTA," added Eitan Konstantino, PhD, President and CEO of TriReme. "Chocolate is a great addition to our line of proprietary peripheral PTA catheters already available in the US, Europe and Asia. We are thrilled with Dr. Mustapha's initial US experience and believe that Chocolate will provide substantial clinical benefits to patients suffering from peripheral vascular disease, both above and below the knee."

About TriReme Medical, Inc.

Based in Pleasanton, California, TriReme Medical, I
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