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Medrad Announces First Use of Cotavance® Catheter in Research

Medrad, a business of Bayer HealthCare AG, today announced first use of the next-generation Cotavance® catheter in a research setting with the start of patient enrollment in the ev3 DEFINITIVE™ AR (Anti-Restenosis) study. ev3 is part of Coviden, a leading global healthcare products company. DEFINITIVE AR is a European pilot study (1) designed to address the challenge of restenosis (narrowing of a blood vessel) in patients with peripheral arterial disease (PAD). The study uses Medrad Interventional's Cotavance® paclitaxel coated balloon angioplasty catheter with Paccocath® technology in combination with Covidien's SilverHawk® and TurboHawk™ plaque excision systems.

The Cotavance catheter used in the study is the next generation device designed to incorporate a precise paclitaxel coating process for controlled drug dosing and a new catheter platform with a full range of catheter sizes. The Paccocath technology is a proprietary drug matrix applied to the balloon of the angioplasty catheter consisting of paclitaxel, long used in drug-eluting stents to treat cardiovascular disease, and Ultravist® 370, a radiologic contrast agent.(2) When the balloon is inflated to dilate the narrowed vessel, paclitaxel is delivered directly to the diseased area.

"The original Cotavance product is the only peripheral paclitaxel eluting balloon catheter using Paccocath technology," said Jack Darby, Senior Vice President of Medrad Interventional. "We're extremely enthusiastic about the opportunity represented by this advanced Cotavance catheter platform."

DEFINITIVE AR will evaluate whether treating a diseased vessel with plaque excision prior to the use of a drug-eluting balloon (DEB) decreases rates of restenosis compared to DEB treatment alone. DEFINITIVE AR is one of several clinical studies designed to expand treatment options and produce additional long-term data with the Cotavance paclitaxel eluting balloon catheter in the treatment of PAD. Additional planned studies using the next-generation Cotavance catheter include EURO CANAL - a prospective randomized study of patients with infrapopliteal artery stenotic lesions presenting with critical limb ischemia; COPA CABANA - a physician-sponsored study of treatment of instent restenosis in femoropopliteal arteries; and RIVER - a prospective randomized trial for the treatment of superficial femoral or popliteal arteries for FDA approval of Cotavance. Collectively, these studies will enroll approximately 700 patients in more than 90 sites around the world.

The Cotavance catheter is expected to be available in Europe in the second half of 2011. Medrad Interventional is also moving forward with the Investigational Device Exemption (IDE) process as one of the steps in gaining FDA approval for Cotavance product in the United States.

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