

**FOR IMMEDIATE RELEASE**

**DRUG COATED BALLOON TECHNOLOGY SHOWS PROMISING RESULTS IN  
THREE CLINICAL STUDIES PRESENTED AT TCT CONFERENCE**

**Data Demonstrates Ability of the Moxy™ Drug Coated Balloon  
to Inhibit Restenosis in Peripheral and Coronary Arteries**

**September 23, 2010 -- Washington, D.C.** – Lutonix, Inc., headquartered in Minneapolis, MN, today announced six-month data from three separate drug coated balloon studies presented at the TransCatheter Cardiovascular Therapeutics (TCT) meeting this week demonstrated the ability of the Moxy™ Drug Coated Balloon Catheter to inhibit restenosis in both peripheral and coronary arteries. In all three clinical trials, the drug coated balloon therapy demonstrated a clear biologic effect as measured by six month late lumen loss, a common indicator of arterial restenosis post-procedure. No thromboses were observed in any patient treated with Moxy in any of the three trials. The largest of the studies, LEVANT I, enrolled 101 randomized patients with peripheral vascular disease, and demonstrated a 42% reduction in late lumen loss and trend towards decreased reintervention rates at six months for Moxy by direct comparison to conventional angioplasty control. LEVANT I met its primary endpoint of late lumen loss at six months, 0.46 mm versus 1.09 mm (p=0.016).

Data presented from two coronary studies of the Moxy balloon also demonstrated inhibition of neointimal hyperplasia, the tissue growth that causes restenosis. During a special session of the TCT on drug-eluting stents (DES) and drug coated balloons, Prof. Patrick Serruys (Erasmus Medical Center, Rotterdam) presented data from the Lutonix De Novo pilot study and Dr. Laura Mauri (Brigham and Women's Hospital, Boston) shared the results of the PERVIDEO I study.

The 26-patient Lutonix De Novo study utilized Optical Coherence Tomography (OCT) to provide a high resolution measure of biological effect of the Moxy balloon when combined with bare metal stents (BMS) to treat *de novo* coronary lesions. The data showed clear inhibition of neointimal hyperplasia along with good stent coverage and safety outcomes at six months, thereby establishing the potential feasibility of this combined therapy for coronary artery disease.

“The biologic effect of the drug coated balloon was absolutely clear. By OCT, neointimal hyperplasia was significantly less than that historically observed for BMS and approaching that of DES. There is good strut coverage comparable to second generation DES.” said Prof. Patrick Serruys.

In the single-arm 41-patient PERVIDEO I study examining the safety and feasibility of treating bare metal in-stent restenosis, the Moxy balloon showed a change in percent diameter stenosis of 8.5% during the six month follow-up period and a late lumen loss of 0.16 mm. This late lumen loss data is similar to that achieved in drug-eluting stent and previous drug coated balloon trials for in-stent restenosis. Safety data at thirty days and six months was also similar to comparable trials.

“Although this is a small registry study, it affirms the possibility that drug coated balloons may offer a very useful alternative to stents for treating patients with in-stent restenosis.” said Dr. Mauri.

During the Late Breaking Clinical Trials session of TCT, Prof. Dierk Scheinert (Park Hospital and Heart Center Leipzig, Germany) presented the six month outcomes of LEVANT I, a 101-patient prospective, randomized, multicenter study comparing the Moxy balloon to standard balloon angioplasty as treatment for femoropopliteal artery disease in the legs. LEVANT I met its primary endpoint, late lumen loss at six months, with high significance ( $p=0.016$ ). Mean late lumen loss for Moxy was 0.46mm compared to 1.09mm for conventional angioplasty control. In addition to meeting the primary endpoint, the trial showed a trend towards improved patency and decreased revascularizations, thrombosis, and death compared to conventional angioplasty. The anti-platelet regimen was one month for patients without stent placement.

“LEVANT I, like the coronary studies, clearly demonstrates the ability to substantially inhibit restenosis through the use of a drug coated balloon,” said Prof. Scheinert. “To date, there have been two other randomized trials examining the use of DCBs for peripheral disease. Taken as a whole, these results therefore are not only clinically compelling, but extremely significant in advancing our understanding of this emerging therapy,” he added.

LEVANT I sets the stage for LEVANT II, the upcoming IDE trial designed to support the application for US FDA approval. LEVANT II is a global, multicenter trial that will compare the safety and efficacy of the Moxy balloon to standard balloon angioplasty for the treatment of femoropopliteal disease in an even larger patient population.

#### **About the Moxy Drug Coated Balloon**

Moxy is a new drug coated balloon that delivers paclitaxel to the arterial wall in a single, 30-second inflation. The Moxy balloon is very similar to a standard angioplasty balloon, but is coated with paclitaxel (a commonly used anti-proliferative drug) and a carrier molecule that facilitates rapid drug transfer to the arterial wall upon inflation. This proprietary formulation allows Moxy to deliver a therapeutic drug dose that remains resident in the deep layers of the artery wall, inhibiting restenosis, while also allowing for restoration of the inner arterial surface.

#### **About Restenosis**

Restenosis is the re-narrowing of an artery following angioplasty or stenting. The term “in-stent restenosis” refers specifically to re-narrowing within and around a stent previously placed inside an artery. Restenosis is caused by an overgrowth of tissue inside the artery wall at the original treatment site. Restenosis typically occurs within the first 6 months of treatment, and most often results in re-treatment.

#### **About Lutonix, Inc. ([www.lutonix.com](http://www.lutonix.com))**

Lutonix is a venture-backed medical device company based in Minneapolis, MN. The company is dedicated to the development and commercialization of the safest, most efficacious drug coated balloon for the treatment of coronary and peripheral vascular disease. Current investors include Delphi Ventures, Rivervest Ventures, US Venture Partners and Versant Ventures.

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