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**FOR IMMEDIATE RELEASE**

**FIRST PATIENT ENROLLED IN LUTONIX  
DRUG-COATED BALLOON PIVOTAL TRIAL**

*Enrollment at St. John's Hospital Marks Official Start of the  
Largest Randomized Peripheral Drug-Coated Balloon Trial To Date*

**July 25, 2011 – Minneapolis, MN** – Lutonix today announced the first patient enrolled in the LEVANT 2 clinical trial, a global, multicenter, randomized trial evaluating the safety and efficacy of the Moxy™ Drug Coated Balloon compared to a standard angioplasty balloon for the treatment of peripheral arterial disease (PAD). The first case was performed at St. John's Hospital in Springfield, IL by Dr. Jeff Goldstein.

LEVANT 2 is the first drug-coated balloon IDE trial to be approved by the FDA, and is being conducted to support a PMA application for US approval of the company's Moxy balloon. The trial is expected to randomize approximately 476 patients at up to 55 hospitals worldwide. LEVANT 2 is the largest randomized peripheral drug-coated balloon trial to date, and one of the largest peripheral vascular studies ever conducted.

Randomized patients in LEVANT 2 will be followed for a total of 5 years and independent core laboratories will verify trial outcomes. The primary safety endpoint is a composite of freedom from all-cause peri-operative death and freedom at 1 year from amputation, re-intervention and death. The primary efficacy endpoint is primary patency at 1 year. Dr. Kenneth Rosenfield (Massachusetts General Hospital, Boston MA) and Prof. Dierk Scheinert (Heart Center Leipzig/Park Hospital, Leipzig Germany) are the co-principal investigators of the trial.

“We are very pleased to be the first center to contribute to such an important trial. We believe drug-coated balloons may play an important role in the future of peripheral interventions, and we are proud to be involved in such a well-designed, carefully controlled trial to explore this promising new therapy,” said Dr. Goldstein, site principal investigator at St. John's Hospital.

Co-investigator Dr. Krishna Rocha-Singh added, “With 8-12 million patients known to suffer from PAD and a paucity of durable, highly effective therapies, patients and physicians are in need of a game-changing treatment modality. The LEVANT 2 trial will help us determine whether a drug-coated balloon can fill this gap.”

Drug-coated balloons have received growing attention in recent years as physicians increasingly look for effective ways to treat diseased leg arteries without having to leave a permanent stent implant behind. Like the drug-eluting stents commonly used in the heart, the Moxy balloon delivers

a powerful restenosis-fighting drug to the artery. However, unlike a stent, the Moxy balloon is removed from the body after use, leaving nothing but the drug behind in the artery.

Physician enthusiasm for the drug-coated balloon concept has been bolstered by encouraging results from early trials like LEVANT 1, a precedent study to LEVANT 2. LEVANT 1 was a 101-patient randomized trial in which the Moxy balloon was compared to standard angioplasty for the treatment of diseased femoropopliteal arteries. The trial showed the Moxy balloon had the ability to safely and substantially inhibit restenosis.

“There is tremendous enthusiasm within the medical community about the potential for drug-coated balloons to improve outcomes for our patients,” explained Dr. Rosenfield. “However, because the field is young, we need data from large, randomized controlled clinical trials that are independently validated. Because of its scientific rigor, LEVANT 2 will help address this need. On behalf of Dr. Scheinert and myself, we congratulate St. John’s on their enrollment of the first patient in this landmark trial.”

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

The Moxy balloon is very similar to a standard angioplasty balloon, but is coated with an anti-restenotic drug designed to help keep arteries open and free from re-blockage. During the procedure, the Moxy balloon is inflated for 30 seconds during which it opens up the artery to restore blood flow, and delivers the drug to the artery wall. The Moxy balloon is then removed from the body leaving nothing behind but the drug coating, which works inside the artery over time to prevent restenosis. The Moxy balloon is an investigational device, which is not approved for, or available for sale in, the United States.

### **About Restenosis**

Restenosis refers to the re-narrowing of an artery following angioplasty or stenting. Restenosis is caused by an overgrowth of tissue inside the artery, typically in response to injury caused at the original treatment site. Restenosis often occurs within the first 6 months following an intervention, 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 a safe, efficacious drug-coated balloon for the treatment of coronary and peripheral vascular disease. Current investors include Delphi Ventures, RiverVest Ventures, US Venture Partners, Versant Ventures, Warburg Pincus and The Vertical Group.

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