

## FOR IMMEDIATE RELEASE

### LUTONIX ANNOUNCES ACHIEVEMENT OF SIGNIFICANT MILESTONES AND ADDITIONS TO EXECUTIVE LEADERSHIP TEAM

*Company Receives FDA Approval to Initiate Pivotal IDE Drug-Coated Balloon Trial; CE Mark and ISO Certification Granted*

*Shawn McCormick and Leslie Trigg  
Named to New Senior Management Posts*

**June 28, 2011 – Minneapolis, MN** – Lutonix today announced receiving approval from the US Food and Drug Administration to begin enrollment in its LEVANT 2 IDE clinical trial for the treatment of peripheral arterial disease (PAD), along with receipt of CE Mark for its drug-coated balloon and ISO certification. Lutonix is the first company to receive approval from the FDA to initiate a drug-coated balloon trial.

The company also announced two new additions to its leadership team. Shawn McCormick was named Chief Operating Officer and will oversee manufacturing, R&D, finance and administration for the company. Leslie Trigg was named Executive Vice President, Marketing and Commercial Strategy and will oversee all commercialization aspects of the business.

#### **LEVANT 2 Trial Set to Begin**

LEVANT 2 is a global, multicenter, randomized study evaluating the safety and efficacy of the Moxy™ Drug Coated Balloon compared to a standard angioplasty balloon for treating diseased leg arteries above the knee. The trial is designed to support an application to the US FDA for approval of the Moxy balloon. Co-principal investigators for this international study are Dr. Ken Rosenfield (Massachusetts General Hospital, Boston MA) and Dr. Dierk Scheinert (University of Leipzig, Leipzig Germany).

The LEVANT 2 trial was preceded by LEVANT 1, a multi-center, prospective randomized trial of 101 patients with PAD. In this study, the Moxy balloon was compared to standard angioplasty. Data presented during the 2010 Transcatheter Cardiovascular Therapeutics meeting showed that the Moxy balloon had the ability to safely and substantially inhibit restenosis.

“Finding a durable treatment for PAD has proven to be one our most difficult clinical challenges,” said Dr. Rosenfield. “PAD patients are in great need of better treatment options. This trial is an important step forward in evaluating a promising new therapy.”

According to the National Institutes of Health, 8-12 million people in the United States have PAD. Although conventional stent and balloon treatments are available, achieving long-term effectiveness remains a challenge. Drug-coated balloons may offer a much-needed new solution by combining the therapeutic simplicity of balloon angioplasty with the power of an anti-restenotic drug to help keep the artery open over time. The DCB technology enables physicians to deliver the drug directly to the artery without leaving a permanent implant such as a stent behind.

## **Executive Leadership Additions**

Prior to joining Lutonix, Shawn McCormick previously served as Chief Financial Officer of ev3, Inc. and was instrumental in improving the company's operating performance, ultimately leading to a successful acquisition by Covidien. Prior to ev3, Shawn spent 17 years with Medtronic in a variety of senior management roles including Vice President of Finance for the spinal division and Vice President, Corporate Development.

Leslie Trigg previously served as Chief Business Officer of AccessClosure, leading the sales and marketing efforts behind the launch of a new vascular closure device. Prior to AccessClosure, she led the commercial introduction of a new PAD therapy as VP of Marketing for FoxHollow. Leslie also has held commercialization roles of increasing responsibility at Guidant, Pro-Duct Health and Cytoc. She currently serves on the board of directors for Cardiovascular Systems, Inc., a publicly traded medical device company in the peripheral vascular space.

"We are thrilled to be able to complement our strong regulatory, clinical, scientific and R&D capabilities with the extensive operating experience Shawn and Leslie bring to the company," said Dr. Dennis Wahr, CEO of Lutonix. "Given their combined leadership track record, we are proud to have them join the organization and know their contributions will advance the company toward its mission with quality and speed."

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

The Moxy balloon delivers an anti-proliferative drug to the artery in a single, 30-second inflation and then is removed from the body. The Moxy balloon is very similar to a standard angioplasty balloon, but is coated with paclitaxel and a carrier molecule that facilitates rapid drug transfer upon inflation. This proprietary formulation allows delivery of a therapeutic drug dose to inhibit restenosis, while permitting restoration of the artery's inner surface. The Moxy balloon 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. Anti-proliferative drugs such as paclitaxel are used in devices like drug-eluting stents to prevent restenosis.

### **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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