Lutonix Announces Achievement of Significant Milestones and Additions to Executive Leadership Team

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MINNEAPOLIS, June 28, 2011 /PRNewswire/ -- 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
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