

PRESS RELEASE: Lutonix Inc. Announces First Patient Enrollments in Three Separate Clinical Trials

Lutonix Inc. initiates trials to study their drug coated balloon technology in the coronary and peripheral vasculature.

Minneapolis, MN., July 27, 2009 — Lutonix Inc., a privately held medical device start-up, today announced that patient enrollment is underway for its three simultaneous first-in-human clinical trials. The three studies are designed to test whether the proprietary Lutonix Drug Coated Balloon (DCB) Catheter is safe and effective in the treatment of vascular narrowing.

The PERVIDEO I Registry

The PERVIDEO I Registry is investigating the Lutonix Drug Coated Balloon Catheter for the treatment of coronary bare metal stent in-stent restenosis (ISR). The study will assess various safety and clinical endpoints over a two year period. Dr. Laura Mauri, Associate Physician and Director of Biometrics at Brigham & Women's Hospital in Boston, MA is serving as the Principal Investigator for the study along with Co-Principal Investigator Prof. Detlef Mathey of the Medical Center in Hamburg, Germany. The first patient was enrolled by Prof. Mathey.

"It is very exciting to have the PERVIDEO I study underway," said Dr. Mauri. "The scientific evidence collected from this investigation will support the initiation of large global trials in the near future" she added. Prof. Mathey states, "I have been involved in DCB research for several years now and I believe this technology, if formulated correctly, shows great promise for treating many types of coronary diseases, including bare metal ISR."

The LEVANT I Trial

The LEVANT I Trial is a randomized study designed to test the safety and efficacy of the Lutonix Drug Coated Balloon Catheter in preventing restenosis in the femoropopliteal arteries. Scheduled clinical and safety visits will assess endpoints out to two years.

Study Principal Investigator Prof. Dierk Scheinert, Director of Angiology at the Park-Krankenhaus in Leipzig, Germany states, "The initiation of the LEVANT I study is a major milestone and I am honored to lead such an outstanding group of physician investigators." Prof. Scheinert adds, "The optimal intervention treatment strategy for this population has yet to be discovered, and the DCB technology may mark the next major advancement in peripheral interventions." The first patient was enrolled by Prof. Stephan Duda of the Jewish Hospital in Berlin, Germany.

The Lutonix De Novo Pilot Study

The Lutonix De Novo study will assess the interaction between bare metal stents and the Lutonix Drug Coated Balloon Catheter. Safety and clinical outcome data will be collected over two years. Prof. Patrick Serruys, Chief of Cardiology at Erasmus Medical Center in Rotterdam, the Netherlands is serving as study Principal Investigator. The first patient was enrolled by Dr. Jacques Koolen at Catharina Hospital in Eindhoven, the Netherlands.

President & CEO Dr. Dennis Wahr added, “Lutonix is committed to the principle of clinical excellence and dedicated to substantially improving long term patient outcomes. Through close collaboration with global thought leaders and experienced CROs, we have been able initiate a clinical program designed to provide objective evidence that our DCB formulation is clinically effective.”

About Restenosis

Restenosis is the re-narrowing of an artery experienced by some patients following angioplasty, atherectomy, or stenting. Restenosis is caused by an overgrowth of tissue inside the artery wall at the original treatment site. Restenosis is typically experienced by some patients within the first 6 months of treatment, which most often results in re-intervention or surgery.

About Lutonix, Inc.

Lutonix, Inc., co-Founded in July 2007 by Dennis Wahr, M.D. and Lixiao Wang PhD, is focused on the rapid development and commercialization of the safest and most efficacious drug coated balloon for the treatment of vascular disease in the coronary and peripheral arteries. Lutonix’s drug coated balloon technology is anticipated to enhance and broaden the therapeutic options for patients with vascular disease who may not be ideal candidates for conventional therapies such as balloon angioplasty and stents and for those who are contraindicated for those treatments. Lutonix is a venture-backed medical device start-up based in Minneapolis, MN. Current investors include: Delphi Ventures, Rivervest Ventures, US Venture Partners, and Versant Ventures.

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