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Pluromed Announces Completion of Enrollment in LeGoo™ Cardiac Bypass Clinical Study

Pluromed, Inc. has completed enrollment in its LeGoo™ off-pump coronary artery bypass clinical study, based on a protocol reviewed by the U.S. Food and Drug Administration (FDA). When completed, the report of the study will be filed with the FDA as part of the company's submission for U.S. regulatory approval of LeGoo™.

(PRWEB) -- Pluromed, Inc. today announced that it has completed enrollment in its LeGoo™ off-pump coronary artery bypass clinical study, which is evaluating the clinical efficacy of LeGoo™ as compared to a traditional vessel loop. This prospective, randomized trial commenced enrollment in 2008 and has reached its goal of 110 patients, enrolled at 9 hospitals in 4 countries. Principal investigators for the trial were Gerhard Wimmer-Greinecker, M.D., Ph.D., Ardawan Rastan, M.D., Ph.D., Volkmar Falk, M.D., PhD, Olivier Bouchot, M.D., Jan Gummert, M.D., Ph.D., Jean-Philippe Verhoye, M.D., Ph.D., Louis Perrault, M.D., Ph.D., Anno Diegeler, M.D., Ph.D. and Jos G. Maessen, M.D., Ph.D.; Dr. Valavanur A. Subramanian, Chairman of the Department of Cardiothoracic Surgery at The Lenox Hill Heart and Vascular Institute of New-York, served as Chairman of the study's Data Safety Monitoring Board.

Pluromed's LeGoo™ is a polymer-based device which is comprised of a non-toxic and biocompatible gel that exists as a liquid at low temperatures and rapidly transitions to a solid at body temperature, forming a plug that can occlude blood vessels. LeGoo™ is injected into a blood vessel that is intended to be occluded, where it stays in a "plug" form for several minutes allowing the surgeon to work in a bloodless field. The gel dissolves with time (spontaneously) or can be reversed back to liquid instantly by cooling the site with ice or irrigating with cold saline. Once dissolved below a minimum concentration, the polymer cannot re-solidify.

The primary purpose of the study is to demonstrate the clinical safety and efficacy of LeGoo™ in comparison to a standard vessel occlusion method (i.e. vessel loops). Although LeGoo™ is also designed for use in other vascular surgeries where temporary vessel occlusion is desired, this study specifically focused on the use of LeGoo™ in off-pump coronary bypass (OPCAB), as a most sensitive model of adverse changes that may occur at any vascular site outside of the neurovascular system. The primary endpoint is the proportion of anastomoses (process of suturing the bypass graft to the coronary artery) in which satisfactory hemostasis is achieved.

Dr. William E Cohn, Director of Minimally Invasive Surgery Technology at Texas Heart Institute, is the medical director of the study. "With enrollment completed, our focus now turns to data monitoring, completion of follow up and preparation for filing with the U.S. Food and Drug Administration and for primary endpoint publication" said Dr. Cohn. "We are grateful to all the trial investigators who have worked so diligently to reach this milestone."

"This important trial is the latest example of the commitment of leading vascular and cardiovascular surgeons, who seek less traumatic methods to improve patient outcome", said Jean-Marie Vogel, President and CEO of Pluromed. "We appreciate the participation of the 22 leading physicians and 13 research coordinators, whose efforts led to the successful completion of enrollment."

About Pluromed, Inc.

Pluromed, Inc., Woburn, Massachusetts, founded in 2003, is pioneering the use of atraumatic gel plugs to improve the safety, efficacy and economics of medical interventions. These products potentially address a broad surgery market that includes cardiac and vascular surgery, prostate, kidney and liver surgery, plastic/reconstructive surgery, trauma/battlefield applications and the treatment of kidney stones. They are based on the Company's patented rapid phase transition polymer technology; Pluromed Rapid Transition Polymers (RTP™) are liquid at low temperature and quickly transition to a high viscosity gel at body temperature. Pluromed's BackStop™, a product used in the treatment of ureteral stones, is cleared for human use in Europe, Canada and the United States. LeGoo™ is approved for human use in Europe but is not currently cleared for human use in the USA. In April of 2009, Pluromed received an Accelerator Loan from the Massachusetts Life Sciences Center, a quasi-public agency tasked with implementing Massachusetts' ten-year, $1 billion Life Sciences Initiative. The Accelerator Loan Program seeks to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences by providing working capital to promising early-stage companies. For more information, please visit www.pluromed.com. For more information about the Massachusetts Life Sciences Center, please visit www.masslifesciences.com.

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