

## **Pluromed Receives FDA Approval for its LeGoo® Endovascular Occlusion Gel; Gel Stops Blood Flow During Blood Vessel Surgery**

*Pluromed received FDA approval for LeGoo, a gel that allows surgeons to temporarily stop blood flow during blood vessel surgery without damage to blood vessels.*

([PRWEB](#)) October 05, 2011 -- [Pluromed, Inc.](#), a medical device company pioneering the use of novel injectable plugs, announced today that the FDA has approved LeGoo, a gel that allows surgeons to temporarily stop blood flow during surgery without the use of clamps or elastic loops.

The Company plans to start commercializing LeGoo at select medical centers in the United States in early 2012.

It is necessary to temporarily stop blood flow through vessels that are being joined in surgery. Stopping blood flow prevents flooding of the surgical field with blood, which makes it difficult for the surgeon to clearly visualize placement of the sutures that connect the vessels. LeGoo has been shown to minimize blood flow into the surgical area without damaging blood vessels. Standard tools, such as elastic loops and clamps, do not always allow for a bloodless surgical area and may damage vessels.

LeGoo is a water-soluble, temperature-sensitive gel that is liquid at room temperature. When injected into a blood vessel, it forms a gel plug that molds to the shape of the blood vessel and stops blood flow. Suturing can be performed directly through the gel. Upon completion, LeGoo is dissolved by applying ice directly to the vessel or infusing cold saline. The diluted material will not re-gel once it is dissolved.

“LeGoo is an innovative device that offers surgeons an additional aid during vascular surgery,” said Christy Foreman, director of the Office of Device Evaluation in the FDA’s Center for Devices and Radiological Health, who is quoted in an FDA’s press release of Oct 3, 2011. “The gel’s unique properties may facilitate surgeries that entail the joining or grafting of blood vessels.”

In the same press release, the FDA indicates it reviewed studies showing that LeGoo is biocompatible and non-toxic. The FDA also looked at data from a clinical trial of 110 patients undergoing bypass surgery without stopping the heart (off pump coronary artery bypass).

“LeGoo represents a major advancement in surgical technology because of its ability to control bleeding at the surgical site without damaging the blood vessel,” said Dr William E. Cohn, Director, Minimally Invasive Surgical Technology at Texas Heart Institute in Houston, who acted as the medical director of the clinical trial. “Dr. Cohn has since joined the Board of Directors of Pluromed.

LeGoo is now approved in the United States for temporary endovascular occlusion of blood vessels up to 4mm in diameter below the neck. The company estimates that it represents over 80% of all vascular and cardiovascular surgical procedures in the United States requiring temporary vascular occlusion.

“The FDA has, among other responsibilities, the mission to protect the public health by assuring the safety, effectiveness, and security of medical devices”, noted Jean-Marie Vogel, Pluromed’s President and Chief Executive Officer. “The approval of LeGoo shows that it can fulfill that mission and yet approve innovative devices with the potential to change the way surgery will be done in the future.”



Pluromed is completing the build-out of an 8,600 square foot manufacturing facility in suburban Boston, Massachusetts, to accommodate rollout of its commercial products in both domestic and overseas market.

It is estimated that each year over 20 million U.S. patients undergo procedures that necessitate temporary occlusion of blood vessels.

#### About Pluromed

Founded in 2003, Pluromed, Inc. (<http://www.pluromed.com>) is a medical device company pioneering the use of novel injectable plugs to improve the safety, efficacy and economics of surgery and other medical interventions. The Company develops, manufactures and markets a family of disposable medical devices based on patented rapid reverse thermosensitive polymer (RTP™) technology that generates unique polymers; they exist as liquids at low temperature and quickly transition to viscous gels at body temperature. Pluromed's strategy is to develop devices that will be used to control bleeding in a broad array of procedures including cardiac, vascular, plastic and reconstructive surgery; kidney and liver cancer therapies; and trauma/battlefield applications, etc.

The Company's LeGoo Endovascular Occlusion Gel is approved in the United States for temporary endovascular occlusion of blood vessels below the neck up to 4mm in diameter. It is CE Marked in the European Community, where it has been used in over 1,000 surgical procedures as diverse as beating heart surgery (coronary artery bypass without the use of a heart-lung machine), bypass of the leg (in patients treated for peripheral vascular disease) and microvascular reconstruction.

The Company is at advanced stages of development of its first interventional oncology product line, Lumagel™. Lumagel has the potential to significantly improve the efficacy of cancer therapies and expand the market for partial nephrectomy, hepatic resection, radiofrequency (RF) ablation and localized chemotherapy.

Pluromed also developed and manufactures BackStop®, a gel used to facilitate the treatment of kidney stones, for which the Company has a worldwide distribution agreement with Boston Scientific. BackStop is cleared by the FDA for use in the prevention of kidney stone migration during intracorporeal lithotripsy, CE Marked for distribution within the European Community, and approved by Health Canada.

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