



## **Pluristem Moves Intermittent Claudication Indication Forward in Europe Through Collaboration with Cato Research**

*14 million people in the U.S. suffer from intermittent claudication, a subset of peripheral artery disease, costing \$2.5 billion per year*

**HAIFA, ISRAEL, Aug 13, 2012 --** [Pluristem Therapeutics, Inc.](#) (NASDAQ:PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced it has selected Cato Research as its contract research organization (CRO) for the German portion of the Company's Phase II trial in intermittent claudication (IC) under the auspices of the Paul-Ehrlich Institute (PEI). Cato will serve as Pluristem's applicant for its IC Clinical Trial Application to the PEI and to the ethics committees of the three study sites where the trials will be conducted. The trial will evaluate the safety and efficacy of Pluristem's PLacental eXpanded (PLX-PAD) cells in treating IC, a subset of peripheral artery disease (PAD). The prevalence of IC in the United States alone is approximately 14 million patients, representing a cost of approximately \$2.5 billion annually to the healthcare system. (References: The SAGE Group and HCUP 2007 Inpatient Data)

Cato Research is a full-service contract research and development organization with international resources. Cato is dedicated to helping pharmaceutical and biotechnology companies efficiently and expeditiously navigate the regulatory approval process in bringing new drugs, biologics, and medical devices to the people who need them.

In addition to Germany, Pluristem's multinational Phase II trial in IC will also include 11 sites in the United States and 2 sites in Israel with the US Food and Drug Administration (FDA) already approving the United States portion of this study. The trial will enroll 150 patients in a randomized, double blinded, placebo controlled study evaluating two doses of either 150 or 300 million PLX cells given intramuscularly three months apart. The primary endpoint of the trial will be maximum walking distance achieved on a treadmill at 12 months.

"Cato is a global organization with sixteen offices around the world, seven of which are in Europe. If we choose to open more clinical sites in the European Union, Cato has the resources to support us efficiently with the regulatory submission to the different regulatory agencies," stated Zami Aberman, Chairman and CEO of Pluristem. "IC afflicts approximately 14 million people in the United States alone. If we are successful in our trials, our proprietary 3D technology for manufacturing our PLX-PAD 'off-the-shelf' product will enable us to meet the demand to treat such a large population of patients across the world."

### **About Intermittent Claudication:**

Intermittent Claudication (IC) is a subset of Peripheral Artery Disease (PAD) caused by atherosclerosis of the lower extremity arteries. IC is characterized by muscle pain, such as aching, cramping, numbness or a sense of fatigue classically in the calf muscle, which occurs during

exercise, such as walking and is relieved by a period of rest. The prevalence of IC in the United States alone is approximately 14 million patients and representing a cost of approximately \$2.5 billion annually to the National Healthcare Bill (References: The SAGE Group and HCUP 2007 Inpatient Data).

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. ([PSTI](#)) (TASE:PLTR) is a leading developer of placenta-based cell therapies. The Company's patented PLX (PLacental eXpanded) cells are a drug delivery platform that releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory and ischemic diseases. PLX cells are grown using the company's proprietary 3D micro-environmental technology and are an "off-the-shelf" product that requires no tissue matching prior to administration. Pluristem is focusing on the development of PLX cells administered locally to potentially treat systemic diseases and potentially obviating the need to use the intravenous route.

Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease when given locally. Additionally, Pluristem is developing PLX-PAD for cardiac ischemia, PLX-RAD for Acute Radiation Exposure, Bone Marrow Transplant Failure and Chemotherapy induced Bone Marrow Aplasia, PLX-ORTHO for orthopedic indications and PLX-PAH for Pulmonary Hypertension in collaboration with United Therapeutics. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

Pluristem has a strong patent portfolio, company-owned GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned management team. For more information visit [www.pluristem.com](http://www.pluristem.com), the content of which is not part of this press release. Follow Pluristem on Twitter@[Pluristem](#).

[CLICK HERE](#) to watch a video where CLI patients and doctors involved with the clinical trials share their stories, the content of which is not part of this press release.

The Pluristem Therapeutics Inc. logo is available at  
<http://www.globenewswire.com/newsroom/prs/?pkgid=6882>

### **Safe Harbor Statement**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, when we discuss our IC clinical trial, when we discuss how our 3D technology for manufacturing our PLX products will enable us to meet the demand to treat IC patients, when we say that data from two phase I studies in Critical Limb Ischemia indicates that PLX-PAD is safe and potentially effective, or when we discuss how pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, we are using forward-looking statements. These forward-looking statements are based on the current expectations of the management of Pluristem only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the

forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching our clinical trials; our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real surgical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause the actual results or performance of Pluristem to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Pluristem undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Pluristem, reference is made to Pluristem's reports filed from time to time with the Securities and Exchange Commission.

**Contact:**

Pluristem Therapeutics Inc.:

William Prather R.Ph., M.D. Sr. VP Corporate Development  
1-303-883-4954

[William.PratherMD@pluristem.com](mailto:William.PratherMD@pluristem.com)

Daya Lettvin  
Investor & Media Relations Director  
+972-54-674-5580  
[daya@pluristem.com](mailto:daya@pluristem.com)

**Media Contact:**

Matthew Krieger  
Finn Partners – for Pluristem  
+972-54-467-6950  
[matthew@finnpartners.co.il](mailto:matthew@finnpartners.co.il)

# # #