



## **Pluristem Commences U.S. FDA Phase II Clinical Trial for Intermittent Claudication**

***Duke University Medical Center is 1<sup>st</sup> of 5 Sites Already Approved***

**HAIFA, ISRAEL, August 23, 2012 --** Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced it will initiate Phase II clinical trials in the United States in the first week of September 2012 to evaluate the safety and efficacy of its PLacental Expanded (PLX) cells in the treatment of Intermittent Claudication (IC), a subset of peripheral artery disease (PAD). The U.S. Food and Drug Administration (FDA) had granted the Company clearance to start the Phase II clinical trial in April of this year.

Pluristem has already received Institutional Review Board (IRB) approval for the trial protocol for five out of the eleven U.S. clinical site locations via its relationship with Western IRB, which has approved Pluristem's protocol.

Site initiation will begin on September 5<sup>th</sup> at Duke University Medical Center with other sites becoming active in the weeks following. Pluristem also plans to initiate sites in Europe and Israel in parallel to the eleven U.S. sites.

Dr. Manesh Patel, the study's Lead Principal Investigator at Duke commented, "We are pleased to participate in the clinical trial process of this novel technology. Duke University Medical Center participated as a clinical site in Pluristem's Phase I/II trial using PLX-PAD cells in critical limb ischemia (CLI). We are excited to lead this next phase of trials exploring its potential use for the significant number of patients with peripheral artery disease."

Pluristem's IC Phase II trial will evaluate the safety and efficacy of two doses of PLX-PAD cells versus placebo, administered via intramuscular injections. The study protocol is comprised of approximately 150 patients with IC: Fontaine class IIb, Rutherford category 2-3.

The primary efficacy end point of the trial is the change in the maximal walking distance from baseline during an exercise treadmill test. Secondary endpoints are hemodynamic and quality of life measurements. Safety parameters are also being assessed.

"Having worked with Duke University and Dr. Patel in our Phase I/II trial for PLX-PAD in CLI, we expected to have a very efficient process to begin trials and this has certainly been the case. This IC study is part of several trials for the PAD indication including CLI and Buerger's disease, which we are planning to launch as part of our strategy to provide a comprehensive solution to PAD patients around the world," stated Zami Aberman, Chairman and CEO of Pluristem.

**About Intermittent Claudication:**

IC is a subset of 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. (NASDAQCM: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-BMP 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](https://twitter.com/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 planned IC Phase II clinical trials in the U.S. and elsewhere, when we discuss other trials for the PAD indication including CLI and Buerger's disease, which we are planning to launch, when we discuss that data from two phase I studies indicate that our PLX-PAD is safe and potentially effective for the treatment of end stage peripheral artery disease, 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)

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