Pluristem Receives U.S. FDA Clearance for Phase II Clinical Trial in Intermittent Claudication

Haifa, Israel –April XX, 2012 -- Pluristem Therapeutics, Inc. (NasdaqCM: PSTI; TASE: PLTR), announced today that the United States Food and Drug Administration (FDA) has granted the company clearance to start a Phase II clinical trial using the company's PLX-PAD cell product candidate for the treatment of Intermittent Claudication (IC), a subset of peripheral artery disease (PAD).

Pluristem's IC Phase II trial will evaluate the safety and efficacy of two doses ($150x10^6$ and $300x10^6$) of PLX-PAD cells versus placebo administered via two intramuscular injections (day one and week twelve post initial injection). The study population will be comprised of 132 patients (44 in each cohort) with IC, Fontaine class IIb; Rutherford category 2-3, in approximately 10 U.S. clinical sites.

The primary efficacy end point of the trial will be the change in the Maximal Walking Distance from baseline during an Exercise Treadmill Tests. Secondary endpoints will include hemodynamics and quality of life measurements. Safety parameters will also be assessed.

"We are excited to receive the world's FDA first clearance for an Intermittent Claudication clinical trial using allogeneic cell therapy as a potential preventive treatment for IC", said Zami Aberman, Chairman and CEO of Pluristem. "We believe that our approach of repeatable intramuscular injections will potentially enable to boost the healing process of our patients. In this trial, we will take benefit of our "off-the-shelf" PLX properties achieved by our three dimensional (3D) proprietary technology platform for efficient, controlled, mass production of cell therapy product candidates, for the treatment of millions of IC patients around the world."

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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. (NasdaqCM: PSTI; TASE: PLTR) is the leading developer of placenta-based cell therapies. The company's patented PLX (PLacental eXpanded) cells are drug delivery platform that releases a cocktail of therapeutic proteins in response to a variety of local and systemic ischemic and inflammatory diseases. PLX cells are grown using the company's proprietary 3D micro-environmental technology and are off-the-shelf products that require no tissue matching or immune-suppression treatment prior to administration.

Pluristem's first product candidate, PLX-PAD, has undergone a comprehensive clinical development plan that has been recognized by both the European Medical Agencies (EMA) and FDA. PLX-PAD targets a population of approximately 20 million patients in the Peripheral Artery Disease (PAD) market. Data from two Phase I clinical trials indicate that PLX-PAD is safe and potentially effective for the treatment of end stage PAD. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective for other ischemic and inflammatory indications such as heart disease, muscle injury, inflammatory bowel disease and radiation as an alternative to bone marrow transplantation. Pluristem has a strong patent portfolio, company-owned GMP certified manufacturing and research facilities, strategic relationships with specialty pharmaceutical and major research institutions and a seasoned management team. For more information visit 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.

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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, we are using forward looking statements when we discuss our planned IC Phase II trial, when we discuss the safety and potential effectiveness of PLX-PAD for the treatment of end stage peripheral artery disease, or when we discuss the potential effectiveness of PLX cells in ischemic and inflammatory indications such as heart disease, muscle injury, inflammatory bowel disease and radiation as an alternative to bone marrow transplantation. 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; 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.