Écrit par Pluristem Lundi, 23 Juillet 2012 16:01 -



**HAIFA, ISRAEL, July 18, 2012 -- Pluristem Therapeutics, Inc** . (NASDAQ:PSTI; TASE: PLTR), today announced that in anticipation of initiating a Phase II study using PLX-PAD cells for the **treatment** of **Intermi** 

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(IC), the company has recently entered into a collaborative agreement with CPC Clinical Research (CPC) for services related to enrolling and sustaining clinical sites. This partnership will leverage CPC's clinical study expertise, including patient recruitment, study monitoring, pharmacovigilance, site audits, quality assurance, biostatistics, data management and medical writing.

As previously reported, Pluristem received FDA clearance for a Phase II study using PLX-PAD cells for the treatment of IC. IC, defined as pain during walking, is the most prominent early symptom of peripheral artery disease (PAD). Data from two phase I studies in Critical Limb Ischemia (CLI), the end stage of PAD, indicates that PLX-PAD is safe and potentially effective.

"CPC, led by Dr. William Hiatt, is the world's leading clinical research organization for the treatment of peripheral artery disease and we are excited to collaborate with an organization that is at the forefront of combining science and commerce in the conduct of clinical research," said Zami Aberman, Chairman and CEO of Pluristem. "This study is a continuation of our comprehensive approach for utilizing PLX-PAD for peripheral artery disease."

The IC study population will be comprised of 150 patients with Fontaine class IIb; Rutherford category 2-3 in a dose escalation, placebo controlled, double blinded study.

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"Research into cell-based therapies represents an exciting new strategy to manage patients with disabling peripheral artery disease. Our collaboration with Pluristem and their scientific steering committee has been excellent, ensuring a high quality trial to test this new cell product", said William R. Hiatt, MD, President of CPC Clinical Research and Professor of Medicine University of Colorado, Anschutz Medical Campus.

## **About CPC Clinical Research**

Founded in 1989 by the University of Colorado, CPC Clinical Research is a non-profit, academically led clinical research organization who has responded to the demands of a fast-paced clinical research industry and competitive market for over two decades. CPC, led by William Hiatt, MD, has provided services in all phases of over 140 clinical trials. Dr. Hiatt is currently the Novartis Foundation endowed professor for cardiovascular research in the Department of Medicine, University of Colorado Denver School of Medicine. He is a past-president of the Society for Vascular Medicine and is a fellow in the American Heart Association and the American College of Physicians. He is currently the chair of the American Heart Association Peripheral Vascular Disease Council. CPC is affiliated with the University of Colorado Denver School of Medicine, Denver Health and the National Jewish Medical and Research Center.

# **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

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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, the content of which is not part of this press release. Follow Pluristem on Twitter @Pluristem.

<u>CLICK HERE</u> 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.

**Safe Harbor Statement**