FDA Lifts Clinical Hold of Pluristem's Phase II Intermittent Claudication Study

HAIFA, Israel September 16, 2013 -- Pluristem Therapeutics Inc. (NASDAQCM: PSTI) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold previously placed on the Company's U.S. Phase II Intermittent Claudication (IC) study (IND 15038) on June 4, 2013.

In its letter to Pluristem, the FDA indicated Pluristem had satisfactorily addressed all the clinical hold issues and the Company may proceed with the study.

Zami Aberman, Pluristem's Chairman and CEO commented, "Pluristem applauds the FDA's vigor to resolve this clinical hold as quickly as possible. We look forward to resuming this important study that addresses the growing, costly and potential serious indication of intermittent claudication."

About Pluristem's Phase II Intermittent Claudication (IC) Clinical Trial

Pluristem's Phase II Intermittent Claudication (IC) study uses the Company's PLX-PAD cells. Up to 150 patients will be enrolled in this dose escalation, randomized, double blind, multicenter, multinational, placebo-controlled trial whose primary endpoints at 12 months will be safety and maximal walking distance relative to baseline. The study protocol will be modified by tightening patient's eligibility criteria and by adding oral anti-histamines and a safety follow-up period for 24 hours post study treatment.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. 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 has a strong intellectual property position, 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.

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 the PLX-PAD Phase II Intermittent Claudication (IC) study, we are using forward-looking statements. These forward-looking statements and their implications 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 and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, 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.

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