Pluristem Provides Update on Clinical Status of IC Trials

HAIFA, Israel June 19, 2013 -- Pluristem Therapeutics Inc. (NASDAQCM: PSTI) (TASE: PLTR), a leading developer of placenta-based cell therapies, provided an update today on the status of its clinical trials in Intermittent Claudication (IC):

- As previously announced, on June 4, 2013 the company received notification from the U.S. Food & Drug Administration (FDA) that its U.S. phase II IC trial was put on hold following the hospitalization of a patient with an allergic reaction in the company's IC trial in the United States. The patient, who suffers from a number of severe background diseases (including oxygen-dependent chronic obstructive pulmonary disease) in addition to IC, experienced a rash and shortness of breath following the treatment. She was admitted to a local hospital and discharged the following day after resolution of her symptoms.
- According to FDA regulations, within 30 days of the notification of the clinical hold, the FDA is to provide Pluristem with a letter detailing a list of questions and requests for information from the Company. Pluristem has not yet received this letter.
- In order to accelerate the review of the relevant facts and resolution of the issues, Pluristem has already provided the FDA with additional information and aggregate safety analyses based on the database compiled by the company from its previous clinical studies.
- Since the IC study is a multi-national trial being conducted under identical study designs in both the U.S. and Germany, Pluristem advised the Paul-Ehrlich-Institute (PEI) in Germany about the FDA clinical hold and provided relevant information. Following further communication with the PEI, and in order to maintain consistency among the study protocols, the company has issued an amendment to the protocol putting the IC study in Germany on hold in order to provide more comprehensive analysis, and a risk minimization proposed plan.

Zami Aberman, Pluristem's Chairman and CEO, stated, "We continue to work closely and transparently with the FDA and PEI to address all issues in the IC clinical study. Pluristem is committed to resolve this issue and to provide the regulatory agencies the information needed to ensure the maintenance of patient safety and wellbeing and to move forward with this clinical trial as soon as possible."

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 providing the regulatory agencies the information needed to ensure the maintenance of patient safety and wellbeing in order to move forward with our clinical trials as soon as possible 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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