Pluristem Announces Positive 12-Month Data from the Use of PLX-PAD for the Treatment of Critical Limb Ischemia

The Company's Phase I Trials, Regulated by the FDA & the Paul Ehrlich Institute, Met All Endpoints

HAIFA, ISRAEL, November 2, 2011 – Pluristem Therapeutics, Inc. (NASDAQ:PSTI; TASE:PLTR) today announced positive 12-month data from its Phase I open-label, dose-escalation clinical trials conducted under protocols approved by the Food & Drug Administration (FDA) in the USA and the Paul-Ehrlich-Institute (PEI) in Germany. PLX-PAD cells met all the clinical studies' protocol endpoints, demonstrating a safe immunologic profile at all dosage levels and found to be potentially effective in treating patients suffering from Critical Limb Ischemia (CLI).

Edwin Horwitz, MD, PhD, Associate Professor of Pediatrics at the Children's Hospital of Philadelphia, President of the International Society for Cellular Therapy (ISCT), and Chairman of Pluristem's Scientific Advisory Board, will present the 12-month follow-up results at the World Conference on Regenerative Medicine on November 3, 2011 in Leipzig, Germany.

The endpoints of these Phase I trials included data on tumorigenesis, adverse events, immunological reactions, laboratory and ECG findings. The results of these two trials are combined for reporting purposes.

No malignancies were reported and all serum sample levels of tumor markers (PSA, CEA, CA125, AFF and NSE) were within normal range for all patients tested. Monitoring for malignancies was required only in the clinical trial conducted in Germany. It was concluded that treatment with PLX-PAD cells does not induce tumorigenesis.

No clinical evidence of adverse events or toxicities related to the intramuscular (IM) administration of PLX-PAD cells was observed in twenty-six of twenty-seven patients. Only one patient in the US trial experienced a transient local cutaneous inflammation after PLX-PAD was administered. A transient change was noted in the leukocyte and lymphocyte count in the patients, which returned to pre-injection baseline levels within 7 days and without evidence of absolute lymphopenia. No ECG abnormalities were

detected during the treatment and monitoring periods.

Additionally, five of the twenty-seven patients received a double dose of PLX-PAD cells from the same placental batch two weeks apart without evidence of adverse events.

Based on the above data it was concluded there were no significant safety issues and PLX-PAD cells can be safely given IM to patients without matching, even if the patients are dosed twice from the same placental source.

Trends Towards Efficacy Based on Amputation Free Survival (AFS):

According to the study protocols, the clinical follow up was completed 3 months after the administration of PLX-PAD cells. During that time, statistically significant improvements were noted for the following efficacy parameters (see press release announcement from September 14, 2011):

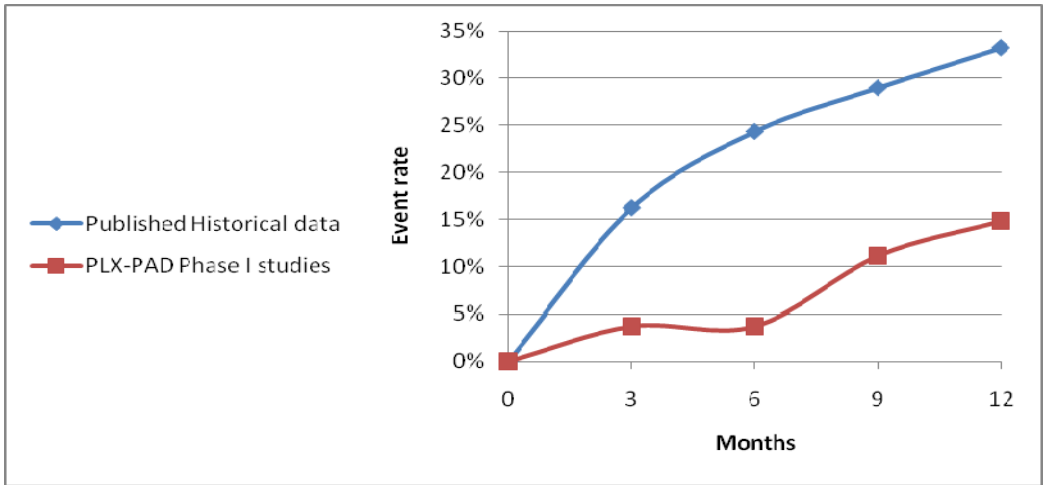
- Ankle-Brachial Index (ABI) - a measure of blood flow (P=0.033).
- Transcutaneous Oxygen Pressure (TcPO2) - a measure of tissue oxygenation (P=0.05)
- Quality of Life (QoL) - (P< 0.001)
- Visual Analogue Score (VAS) – a measure of pain (P=0.013)

The European Medical Agencies (EMA) and the FDA require the primary endpoint for CLI pivotal clinical trials to be Amputation Free Survival (AFS) rate. AFS data was collected during the Phase I studies and compared with another published CLI trial's data.

From a total of twenty-seven patients, four treatment failures occurred during the observation period of twelve months, which resulted in an AFS rate of 85.2%, as opposed to historical control data of 66.8% for the same time period. This corresponded to an event rate of 14.8%, as opposed to historical control data showing a 33.2% event rate, as outlined in Table 1 below.

Therefore, based on the endpoint of AFS at 12 months, it was concluded there is a trend towards efficacy of PLX-PAD cells in the treatment of CLI.

Table 1: Cumulative Event Rate Comparison



Dr. Horwitz stated: “AFS is the single most important endpoint in CLI clinical trials. Even though these Phase I trials were not controlled studies, the data collected in these trials on AFS indicate significant potential for PLX-PAD cells in treating CLI patients”.

“The safety data from these trials provide strong evidence that supports our business approach of using allogeneic PLX cells for various indications.” said Zami Aberman, Chairman and CEO of Pluristem. “The clinical trials also demonstrated that PLX cells possess superior properties enabling a second, same placental batch, dose administration, which will be translated into a logistical advantage when the cells are commercialized. Additionally, the ability to administer our "off-the-shelf" cells in two doses without the need for tissue matching could potentially prolong the therapeutic effect of PLX cells in the treatment of CLI, via a "booster" dose.”

About the Study Protocols

Two Phase I clinical studies were conducted in the USA and Germany in accordance with protocols approved by the FDA and the PEI, respectively. Twenty-seven CLI patients were treated with PLX-PAD cells and followed for 12 months following the administration of the initial doses in the USA and for 24 months in Germany. During the clinical follow up period patients underwent clinical examinations, blood flow measurements, scores for quality of life and pain, ECGs and peripheral blood samples were drawn during their follow up visits for chemistry and immunological analysis.

Twenty-two of the twenty seven patients in the US and Germany received a single course of PLX-PAD cells with either 30 or 50 IM injections above and below the knee of the afflicted limb in a treatment that took, on average, approximately 20 minutes to complete. The remaining five US patients received a double dose of PLX-PAD cells in two courses administered two weeks apart. These five patients received both courses of PLX-PAD cells from the same placental batch. This was done in order to test for a delayed

immunological response. Three dosage levels of 200, 300 and 600 million[1] PLX-PAD cells were evaluated. The five patients treated with the double dose of PLX-PAD cells received each a total dose of 600 million PLX-PAD cells.

About the Immunological Data

From an immunological perspective, the administration of PLX-PAD cells stimulated mostly transient non-specific immunological reactions .These reactions were without clinical significance or symptoms. Additionally, IM injections of up to 300 million PLX-PAD cells did not cause any PLX cell-specific response.

In addition, five patients received a double dose of PLX-PAD cells two weeks apart. There was no evidence of immediate clinical toxicity or adverse events and vital signs remained stable in all patients. Additionally, there were no significant changes noted in routine blood counts during the follow up periods. From an immunological perspective, no significant changes were noted in the patients' lymphocytes including CD3, CD4, and CD8 lymphocyte counts or the CD4/CD8 ratio and in their Natural Killer (NK) cell population. A transient decrease in antigen presenting cells was demonstrated within 24 hours of PLX-PAD administration that returned to pre-PLX-PAD injection levels within one week. This phenomenon may be attributed to the immuno-modulating quality of PLX-PAD cells.

About Pluristem Therapeutics Inc.

Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR) is a leading developer of placenta-based cell therapies. The company's patented PLX (PLacental eXpanded) cells drug delivery platform releases a cocktail of therapeutic proteins in response to a variety of local and systemic inflammatory 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 or immune-suppression treatment prior to administration. The PLX-PAD comprehensive clinical development plan has been recognized by both the EMA and FDA, targeting a sub-population of 20 million patients in the Peripheral Artery Disease (PAD) market.

Data from two Phase I safety and dose determining clinical trials indicate that Pluristem's first PLX product, 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 in nerve pain and muscle damage when administered locally and in inflammatory bowel disease, MS and stroke when administered systemically.

Pluristem has a strong patent portfolio, GMP certified manufacturing and research facilities, strategic relationships with major research institutions and a seasoned

[1] Dose variance equals +/- 10%

management team.

For more information visit www.pluristem.com and follow Pluristem on Twitter @Pluristem, the content of which is not part of this press release.

CLICK HERE to watch a video where CLI patients and doctors involved in 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 the 12-Month data from our clinical trials and the conclusions we derive from it, or when we speak about our potential development of placenta-derived stem cell treatments for a variety of illnesses or when we say that data from two Phase I clinical trials indicate that Pluristem's first PLX product, PLX-PAD, is safe and potentially effective for the treatment of end stage PAD or that Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in nerve pain and muscle damage

when administered locally and in inflammatory bowel disease, MS and stroke when administered systemically. 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.