

# Third Critically III Patient Successfully Treated with Pluristem's PLX Cells Under Compassionate Use

Patient with Blood Cancer, Acute Myeloid Leukemia, Experienced Improved Clinical Condition and Released From Hadassah Hospital

HAIFA, ISRAEL, September 5, 2012 – Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that the Company's Placental eXpanded (PLX) cells were successfully administered to a third patient in Hadassah Medical Center; thus, a series of three life saving compassionate use treatments were completed. The outcome of those treatments potentially suggests that the Company's PLX cells may have significant potential to treat a range of indications of bone marrow diseases.

The latest patient, a 45 year old male, diagnosed with Acute Myeloid Leukemia (AML), a form of blood cancer, underwent chemotherapy to treat the cancerous cells. Treatments with chemotherapy remove cancerous cells as well as normal cells in the bone marrow, leaving the patient needing bone marrow transplantation. The patient received an unrelated (allogeneic) bone marrow transplant. However, he suffered from severe and long standing pancytopenia with associated complications after receiving hematopoietic stem cell transplantations.

Due to the patient's major life threatening condition, 144 days post bone marrow transplantation, PLX cells were injected intramuscularly (IM) at a dose of  $600x10^6$  cells, divided into two administrations, one week apart, under compassionate use treatment. No local or systemic side effects were observed. In addition, the patient's general clinical condition and wellbeing significantly improved, resulting in his release from Hadassah Medical Center.

The series of the compassionate use treatments were led by Professor Reuven Or, Director of the Bone Marrow Transplantation and Cancer Immunology at Hadassah Medical Center in Jerusalem. Professor Or received a special permission by the Ministry of Health of the State of Israel, to try treating critically ill patients with bone marrow transplant failure that have no available alternative treatments, with PLX cells. According to Professor Or, "Following three successful treatments, which were conducted for the first time in the world, in Hadassah Medical Center, we can say that PLX cells from the placenta saved the life of patients suffering from bone marrow failure. We are very encouraged by the results and hope that future clinical trials will show the effectiveness of the PLX cells. I believe that the PLX treatment holds huge hope for patients who suffer from different conditions of bone marrow failure and once approved will be available for every patient who needs it."

This is the third patient, out of three treated, to display impressive clinical improvement following the administration of PLX cells. The first two patients responded, four and nine days respectively, after the second PLX cell administration, with improvement of tri-linage hematopoiesis.

"We are extremely proud that the hard work, research and testing we have put into producing our PLX cells has now actively contributed towards saving the lives of these severely ill patients," said Zami Aberman, Chairman and CEO of Pluristem. "Additionally, with these three patients, we have data to suggest that our PLX cells may be helpful for rescuing both allogeneic as well as autologous bone marrow transplant failures."

Last month, Pluristem announced that it has filed the necessary documents requesting that the U.S. Food and Drug Administration (FDA) grant orphan drug status to its PLacental eXpanded (PLX) cells for the treatment of aplastic anemia, a critical hematological emergency which is treated by a bone marrow transplantation. It has been estimated that there are 30,000 bone marrow transplants each year in the U.S. alone.

## **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 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 is focusing on the use of PLX cells administered locally to 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 and ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

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

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

<u>CLICK HERE</u> to watch a video where CLI patients and doctors involved in the clinical trials share their stories.

#### **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

how the outcome of those three treatments potentially suggests that the our PLX cells may have significant potential to treat a range of indications of bone marrow diseases, when we say that we have data to suggest that our PLX cells may be helpful for rescuing both allogeneic as well as autologous bone marrow transplant failures, 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 when we say that Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis. 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 forwardlooking 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 forwardlooking 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.

#### Contact:

### **Pluristem Therapeutics Inc.**

William Prather R.Ph., M.D. Sr. VP Corporate Development 1-303-883-4954 William.PratherMD@pluristem.com Daya Lettvin
Director Investor & Media Relations
+972-54-674-5580
daya@pluristem.com

# **Media Contact**

Matthew Krieger Finn Partners – for Pluristem +972-54-467-6950 matthew@finnpartners.co.il