

#### Pluristem's CEO Letter to Shareholders

HAIFA, ISRAEL, May 23, 2012 – <u>Pluristem Therapeutics</u>, <u>Inc</u>. (NASDAQCM:PSTI; TASE: PLTR) today announces the below CEO letter to shareholders.

Dear Shareholders,

The past few months have been both busy and exciting for Pluristem. We have made great strides towards executing our strategy of developing a patient friendly, minimally invasive cell therapy solution that can be used to treat a wide range of life-threatening diseases. Our whole team was moved and proud of the remarkable recovery of the seven year old girl we recently treated in a compassion treatment with our PLX cells. I believe that this case reminds us all that our first and primary goal is to help save the lives of patients.

I am happy to share with you Pluristem's most recent achievements, including the impact our PLX cell treatments are already having on patients around the world, and the potential they hold for millions more.

## **Clinical Activities**:

Following two unsuccessful bone marrow transplants, a seven year old girl suffering from aplastic bone marrow disease was given two doses of PLX cells intramuscularly, approximately one week apart. The compassionate use of our cells saved her life and approximately 10 days following the last administration of PLX cells, the patient's hematological parameters began to significantly increase, an effect that has persisted to date.

The potential ramifications: PLX cells may be effective in supporting bone marrow transplantation as well as other potential indications where bone marrow may be suppressed, such as radiation and chemotherapy. Additionally, this case validates the work we have done in animals using our PLX cells in Acute Radiation Sickness (ARS) and provides another data point to our approach that PLX cells can be administered locally into skeletal muscle, distant to the target organ, and obtain efficacious systemic effects.

Pluristem received U.S. Food and Drug Administration (FDA) clearance to begin a Phase II clinical trial using PLX-PAD intramuscularly for the treatment of Intermittent

Claudication (IC), a subset of peripheral artery disease (PAD). The trial will evaluate the safety and efficacy of two doses (150x10<sup>6</sup> cells and 300x10<sup>6</sup> cells) of PLX-PAD versus placebo administered via one or two intramuscular (IM) injections. The study population will be comprised of IC patients, Fontaine class IIb; Rutherford category 2-3 and will be conducted at several leading U.S. clinical sites.

**Key achievement:** The FDA allowed Pluristem to test PLX-PAD in less severe cases of critical limb ischemia (CLI) patients using minimally invasive IM cell therapy administration.

Pluristem plans to initiate a Phase I/II trial of PLX-PAD in patients suffering from muscle injuries related to hip replacement surgery in Germany, upon regulatory approval. An Investigational Medicinal Product Dossier (IMPD) with the Paul-Ehrlich-Institut (PEI) was filed.

# **Pre-Clinical Activities:**

Results of two successful pre-clinical trials using our PLX cells for two cardiac indications, acute myocardial infarction (AMI) and diabetic diastolic heart failure were announced. In the AMI study, PLX cells proved to effectively reduce the area of infarction and improve cardiac hemodynamic parameters. In the diabetic diastolic heart failure study, conducted under the European Commission's Seventh Framework Program (FP7) Collaboration, data suggest that cardiac function in diabetic-induced diastolic dysfunction animals improved following the administration of PLX cells.

*The potential ramifications:* Approximately 624,000 patients in the United States suffer an AMI annually and PLX cells could potentially help those patients. Further, the diastolic heart disease results suggest that PLX cells may inhibit the progression of diabetic-induced diastolic dysfunction as well as possibly repair existing damage.

## **Finance Update:**

In our recent quarterly report on Form 10-Q, we present a strong balance sheet with approximately \$40 million in cash and deposits. We were awarded a grant in excess of \$3 million from the Office of the Chief Scientist (OCS) within the Israeli Ministry of Industry, Trade and Labor. The grant will be used to help fund R&D and clinical trials for the period March to December 2012.

We are on schedule with the build-out of our new manufacturing facility; during the quarter we announced the scale up of bioreactors to allow the production of about 30 billion cells with each reactor run. This scale up together with the new facility, gives us significant competitive advantages for future product commercialization and potential collaborations.

I want to take this opportunity to thank you for being part of Pluristem. We at Pluristem

are encouraged by our positive results and look forward to continuing to build on our successes in the coming months.

Zami Aberman Chairman and CEO

## **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/II 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, 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 letter.

#### 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

#### **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 say that PLX cells may be effective in treating other diseases that affect the bone marrow, when we discuss how we now have several data points to indicate that our PLX cells may work for systemic diseases, when we discuss how diastolic PLX cells may inhibit the progression of diabetic-induced diastolic dysfunction as well as possibly repair the existing damage, when we discuss our plans with respect to clinical studies, when we discuss the competitive advantages our new facility will give us, 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 preclinical 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 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.