Significant Findings in U.S. National Institutes of Health's Trial of Pluristem's PLX-R18 Cells for Treatment of Acute Radiation Syndrome

HAIFA, ISRAEL, February 18, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today the positive results of a recently completed trial conducted by the U.S. National Institutes of Health (NIH) to evaluate PLX-R18 cells to treat bone marrow damaged by exposure to high levels of radiation, such as can occur after a nuclear disaster. Injection of PLX-R18 cells into muscle, as compared to a placebo, resulted in a statistically significant improvement in the recovery of white blood cell, red blood cell, and platelet levels in animals exposed to high levels of radiation. The data also suggested that the treatment may potentially be able to shorten time to recovery. High levels of radiation can destroy the body's ability to produce these three blood lineages, and rapidly regaining that capacity is a key factor in surviving the hematologic component of acute radiation syndrome (ARS), a condition caused by high-dose irradiation that can involve severe, sometimes lethal damage to the bone marrow as well as other physiologic systems and organs.

The objective of this latest trial was to investigate the mechanism of action behind the significant improvement in survival in irradiated mice treated with PLX-R18 that was demonstrated in the NIH's first efficacy study. The results of the current study indicate that intramuscular administration exerts a systemic healing effect on bone marrow, lending further support to the concept that Pluristem's cells work systemically via secretion of therapeutic proteins, although the cells themselves remain in the muscle into which they were initially injected. While additional animal trials are needed prior to U.S. Food and Drug Administration (FDA) approval of PLX-R18 for use in ARS, no human trials would be required because product development is conducted under the FDA's Animal Rule.

"Our PLX-R18 cell product was developed and targeted to become a strong candidate for government procurement programs designed to protect the population in the case of exposure to dangerous levels of radiation. PLX-R18 cells are an off-the-shelf cell therapy product with a long shelf life. They do not require matching before use and can be administered through intramuscular injection. These features are important to facilitate rapid initiation of treatment on a large scale. The study results also support Pluristem's unique approach of injecting cells intramuscularly to enable the cells to remain in the body long enough to respond to signals from damaged tissues and adapt their therapeutic secretion profiles accordingly," stated Zami Aberman, Chairman and CEO of Pluristem.

"We have had a productive working relationship with the NIH's National Institute of Allergy and Infectious Diseases (NIAID), which has independently conducted its studies with PLX-R18 cells provided by Pluristem," Aberman added.

Pluristem is developing PLX-R18 cells for other potential indications including enhancement of engraftment of transplanted hematopoietic stem cells for the treatment of bone marrow deficiency. Trials for this indication are ongoing at Case Western University and Hadassah Medical Center. Data from the NIH studies in ARS are expected to benefit Pluristem's development of its hematology program.

Data from Mechanism of Action Study conducted by NIH

The objective of this study, performed at the Indiana University School of Medicine and funded by the Product Development Support Services Contract HHSN277201000046C from NIAID, was to investigate the mechanism of action behind the results of the NIH's first study of the efficacy of PLX-R18 in ARS. That first study showed a significantly increased 30-day survival and overall survival time of mice treated with PLX-R18 compared to controls.

In the current study, 256 mice were randomized to be injected intramuscularly with PLX-R18 or placebo after total body irradiation, or PLX-R18 or placebo after sham irradiation. Mice were dosed intramuscularly with PLX-R18 cells or a placebo on day 1 and day 5 post-irradiation. Complete blood count parameters and body weight were measured at 8 post-irradiation time points (days 2, 4, 6, 9, 13, 15, 17, and 23), and bone marrow and spleen cellularity and hematopoietic progenitor cells (HPC) were measured at 6 time points (days 2, 4, 6, 9, 13, and 23). Treatment with PLX-R18 cells significantly increased recovery of white blood cells ($p=.0024$), neutrophils ($p=.0026$), monocytes ($p=.0272$), red blood cells ($p<.0001$), platelets ($p=.0005$), hemoglobin ($p<.0001$), and hematocrit ($p<.0001$) at day 23 post-irradiation compared with vehicle-treated control mice. Increases in lymphocytes and percent of neutrophils were also observed, but were not statistically significant. The increase in bone marrow progenitor cells was accelerated in mice treated with PLX-R18 cells as compared to the control group, but this was not statistically significant. The population of bone marrow cells responsible for the earlier stages of new red cell, white cell, and platelet production began to increase before those involved in later stages of production; this is consistent with normal physiology in which the progenitor cells proliferate and replenish the more mature cell populations and eventually the peripheral blood cells.

Published data for ARS study conducted earlier by Pluristem

Previous studies of PLX-R18 cells for ARS were conducted by Prof. Raphael Gorodetsky, head of the Biotechnology and Radiobiology Laboratory at the Sharett Institute of Oncology at the Hadassah Hebrew University Medical Center. Those studies showed an up to four-fold increase in the survival rate of irradiated animals treated with PLX cells versus those treated with a control, as well as improvements in additional parameters. The findings have been published in the peer-reviewed journal PLOS ONE.

About Acute Radiation Syndrome (ARS)

Acute radiation syndrome (ARS) is an acute illness caused by irradiation of the whole body (or a significant portion of it). It follows a somewhat predictable course and is characterized by signs and symptoms that reflect cellular deficiencies and the reactions of various cells, tissues, and organ systems to ionizing radiation. The hematologic component of ARS results from damage to the bone marrow and is characterized by acute decreases in red and white blood cell and platelet counts, which can lead to infection, hemorrhage and death. The gastrointestinal component is characterized by loss of cells lining the intestines, resulting in fluid and electrolyte loss, sepsis, and damage to the intestinal microcirculation, all of which can lead to death. Other components of ARS include potentially lethal damage to the central nervous system and the lungs.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cells are grown using the Company's proprietary three-dimensional expansion 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, 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, forward-looking statements are used in this press release when we discuss that our PLX-R18 cell product is a strong candidate for government procurement programs designed to protect the population in the case of exposure to dangerous levels of radiation or when we discuss our unique approach of injecting cells intramuscularly in order to enable the cells to remain in the body long enough to respond to signals from damaged tissues and adapt their therapeutic secretion profiles accordingly. 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.

Contact:

Pluristem Therapeutics Inc.
Karine Kleinhaus, MD, MPH
Divisional VP, North America
1-914-512-4109
karinek@pluristem.com