

Pluristem and Hadassah Medical Center Announce Significant Data Showing PLX-R18 Cells Improve Bone Marrow Transplantation

In parallel Pluristem and Case Western University announce early data on PLX-R18 in umbilical cord blood transplantation

HAIFA, ISRAEL, March 3, 2015 -- <u>Pluristem Therapeutics Inc</u>. (NasdaqCM: PSTI) TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today strong positive data from a preclinical study of PLX-R18 cells to improve outcomes of bone marrow transplantation. In the study, conducted in conjunction with Hadassah Medical Center's Department of Bone Marrow Transplantation and Cancer Immunotherapy, mice with damaged bone marrow who received intramuscular injections of PLX-R18 cells together with a bone marrow transplant had significantly faster recovery of blood cell production compared to those who received a placebo with the bone marrow transplant. A rapid return to normal blood cell counts is critical for people who require a transplant to replace dysfunctional bone marrow because of diseases such as leukemia or other blood cancers. PLX-R18, Pluristem's second product, is being developed to treat a range of hematologic indications including bone marrow deficiency and complications of bone marrow and umbilical cord blood transplantation.

The objective of the Hadassah trial was to compare the production of blood cells after intramuscular injection with PLX-R18 cells or placebo in the context of transplantation of hematopoietic stem cells obtained from bone marrow. Mice received lethal doses of radiation followed by either a low dose or a high dose of bone marrow cells and either PLX-R18 cells or placebo. Evidence of more rapid recovery was found at the two earliest data collection time points of the study. Nine days after transplantation with a low dose of bone marrow cells and concurrent administration of either PLX-R18 or placebo, those treated with PLX-R18 had statistically significant increases in numbers of platelets and granulocytes as compared to controls; they also had more lymphocytes and total white blood cells, though these increases were not statistically significant. Nine days after transplantation with a high dose of bone marrow cells and concurrent administration of either PLX-R18 or placebo, those treated with PLX-R18 also had statistically significant increases in platelet levels. One week later, at 16 days after a low dose transplantation, those treated with PLX-R18 cells had more platelets than controls, and those treated with PLX-R18 and a high dose of bone marrow had statistically significant increases in platelets, granulocytes and total white blood cells. After a bone marrow transplant patients cannot fight infections or prevent hemorrhage until white blood cell and platelet levels return to normal. The accelerated recovery of platelet and white blood cell levels demonstrated in this study could potentially have important clinical implications.

Alongside the study at Hadassah, a preliminary study was conducted by Hillard M. Lazarus, MD, a Professor of Medicine in the Department of Hematology and Oncology at Case Western Reserve University. The study was part of ongoing research there to test PLX-R18 for use in umbilical cord blood stem cell transplantation. Data in eight mice showed that six weeks after exposure to high doses of radiation, followed by transplantation with human umbilical cord blood cells, three out of four mice who received PLX-R18 cells survived compared to only one out of the four who received a placebo after transplant. At eight weeks after irradiation and transplantation the mice who received PLX-R18 each had a higher percent of hematopoietic cells (CD45+) in their peripheral blood than the surviving control subject. This early finding is encouraging as research continues at Case Western University to study the effects of PLX-R18 on the speed and success of engraftment of umbilical cord blood cells.

"A statistically significant increase in blood counts soon after bone marrow transplant is very meaningful. For the transplant patient, the most critical period for hematopoietic recovery is in the days following the transplant. We were particularly encouraged to see that the administration of PLX-R18 cells resulted in the greatest early improvement when using a lower dose of bone marrow cells. This means we could one day potentially achieve success with lower bone marrow transplant doses, thus addressing both treatment costs and donor availability," stated Professor Reuven Or, Director of the Department of Bone Marrow Transplantation and Cancer Immunotherapy at Hadassah Medical Center and the study's Principal Investigator.

Zami Aberman, Chairman and CEO of Pluristem, added, "Improving the outcomes of bone marrow and umbilical cord blood transplantation can have a significant impact on the treatment of a range of diseases, from blood cancers to immune and genetic disorders. We are happy with the data from preclinical studies of PLX-R18 in the context of transplantation and look forward to continuing our work in these indications with both Hadassah Medical Center and Case Western University."

Additional Information about the Bone Marrow Transplant Study

Seventy-eight irradiated mice were put into four groups receiving: 1) a transplant of four million bone marrow cells, plus an intra-muscular (IM) injection of 1 million PLX-R18 cells on day one and day ten; 2) a bone marrow transplant of eight million cells, plus an IM injection of one million PLX-R18 cells on day one and day ten; 3) a transplant of four million bone marrow cells, plus an IM injection of placebo on days one and ten; 4) a transplant of eight million bone marrow cells, plus an IM injection of placebo on days one and ten. Complete blood counts (CBC) were measured on day nine following the bone marrow transplant and first dose of PLX-R18 or placebo, on day sixteen following the second dose of PLX-R18 or placebo, and on day twenty-three.

Data showed that on day 9, after only one PLX-R18 injection, subjects treated with PLX-R18 plus the lower dose of 4 million bone marrow cells had more platelets and granulocytes than controls (all controls received a transplant), and these differences were statistically significant (p=.0059 and p=.0267 respectively). The subjects injected with PLX-R18 cells also had higher levels of granulocytes and white blood cells overall, although the differences were not statistically significant. The group which received PLX-R18 plus 8 million bone marrow cells also showed

significantly higher platelet counts than controls (p=.0015). One week later, those who received a low dose of bone marrow cells together with PLX-R18 had more platelets than controls, although the difference wasn't significant. Those who received the higher dose of bone marrow cells had significant increases in their levels of platelets, granulocytes and total white blood cells (p=.0053, p=.0122 and p=.0262 respectively). There were no significant differences in numbers of cells between the groups on day 23. Thus, PLX-R18 cells significantly accelerated recovery of several components of normal blood counts.

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, 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, forward-looking statements are used in this press release when we discuss that PLX-R18, is being developed to treat a range of hematologic indications, when we discuss the potential clinical implications of the accelerated recovery of platelet and white blood cell levels demonstrated in the study; the potential future achievement of success with lower bone marrow transplant doses to address both treatment costs and donor availability; the potential significant impact that improving the outcomes of bone marrow and umbilical cord blood transplantation can have on the treatment of a range of diseases, and our continuous work with both Hadassah Medical Center and Case Western University. 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 <u>karinek@pluristem.com</u>