Pluristem Advances Towards U.S. Clinical Trial in PLX-R18 and Announces Principal Investigator

- Dr. Hillard Lazarus of Case Western Reserve University will be the Principal Investigator of the trial
- The trial protocol was cleared by the U.S. FDA
- Incomplete engraftment after HCT is one of several hematologic indications to be targeted by PLX-R18

HAIFA, ISRAEL, September 14, 2016 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced the appointment of Dr. Hillard Lazarus of Case Western Reserve University as the Principal Investigator of the Company's Phase I trial of its PLacental eXpanded (PLX)-R18 cells to treat incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT).

Enrollment for the Phase I trial, which was recently cleared by the U.S. Food and Drug Administration, is expected to begin in the coming months at multiple clinical sites in the U.S. The open label, dose escalating study will evaluate the safety of intramuscular injections of PLX-R18 in 30 patients with incomplete hematopoietic recovery following HCT. Additional endpoints will include changes in platelet and hemoglobin levels, transfusion frequency, frequency of shift from transfusion dependence to transfusion independence, quality of life, and various immunological parameters in the blood.

Dr. Lazarus is a Professor of Medicine at Case Western Reserve University and doctor of Hematology-Oncology at University Hospitals Case Medical Center. He is the George & Edith Richman Professor and Distinguished Scientist in Cancer Research and Director of Novel Cell Therapy. He was Director of the Blood and Marrow Transplant Program for over 25 years. For the past decade, he has been the Principal Investigator of the Case Consortium of the Blood & Marrow Transplant Clinical Trials Network. Having developed many new anti-cancer therapies and sophisticated supportive care technologies, Dr. Lazarus is internationally recognized for his contributions in several areas, including mesenchymal stem cell transplantation and allogeneic blood and marrow transplantation for malignancies. Dr. Lazarus has over 600 publications to his name and is the Editor-in-Chief of both *Bone Marrow Transplantation* and *Blood Reviews*. He is a member of Pluristem's clinical advisory board for the development of PLX-R18 in hematology, and was actively involved in both the selection of the indication and the study design.

“We are pleased and honored that Dr. Lazarus will lead our Phase I trial as Principal Investigator. His extensive experience in the field of hematologic-oncology is an asset to our PLX-R18 development program” stated Pluristem Chairman and CEO Zami Aberman.

“Having previously studied the potential of PLX-R18 in pre-clinical settings to improve outcomes for umbilical cord blood stem cell transplantation, I am eager to lead a clinical trial to explore PLX-R18’s benefits in hematologic recovery following HCT,” commented Dr. Lazarus. “Positive clinical data could support further development of PLX-R18 to increase the success rates of transplants used to treat a broad range of indications.”

About PLX-R18

PLX-R18 is Pluristem’s second cell therapy product cleared for clinical studies by the U.S. FDA. It has already been studied in preclinical models of acute radiation syndrome, support of hematopoietic cell transplants, and side effects of radiotherapy and chemotherapies used to treat cancers. Preclinical data from trials conducted by the U.S. National Institutes of Health, Hadassah Medical Center, and other prominent research institutions have shown that PLX-R18 cells secrete a range of specific proteins that trigger the regeneration of bone marrow hematopoietic cells, thereby supporting the recovery of blood cell production. By this mechanism of action, PLX-R18 could potentially treat a broad range of hematologic indications.

Incomplete Recovery Following HCT

Hematopoietic cell transplantation (HCT) is a standard treatment for a range of conditions, including malignant diseases such as multiple myeloma, non-Hodgkin’s lymphoma, Hodgkin’s disease, and acute myeloid leukemia, as well as non-malignant diseases and autoimmune disorders such as aplastic anemia and thalassemia. The hematopoietic cells for HCT can come from a donor (allogeneic) or from the patient (autologous), and can be harvested from peripheral blood, bone marrow or umbilical cord blood.

In a number of cases, complete hematopoietic recovery following HCT is not reached, and patients are at increased risk of bleeding, infection, anemia, and poor general function. Current treatments include administration of factors stimulating growth of specific blood cell types, such as granulocyte-colony stimulating factor (G-CSF), granulocyte-macrophage colony-stimulating factor (GM-CSF), and erythropoietin. However, a significant number of patients do not respond to growth factors and may require frequent transfusions, which expose them to transfusion-related risks such as allo-sensitization and infections, without providing a curative solution. These are also associated with significant costs.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are

grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

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 expected timing for enrollment for the Phase I trial, when we discuss the planned trial design and its endpoints, when we discuss the potential of positive clinical data to support further development of PLX-R18 to increase the success rates of transplants, and when we discuss the potential of PLX-R18 to treat a broad range of hematologic indications. 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 clinical 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.

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