Pluristem Receives U.S. FDA Clearance to Initiate Clinical Trial of PLX-R18 to Treat Insufficient Hematopoietic Recovery Following Bone Marrow Transplant

- ***Phase I, open-label trial will allow for interim data analysis***
- ***PLX-R18 could potentially treat a broad range of hematologic indications***
- ***Pluristem will pursue early market access for PLX-R18 in the U.S.***

HAIFA, ISRAEL, January 12, 2016 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI , TASE: PLTR), a leading developer of placenta-based cell therapy products, announced today that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application to begin its Phase I trial of PLX-R18 cells to treat incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT). The clinical trial is expected to begin in the first half of 2016.

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 resurgence of progenitor cells, supporting the recovery of blood cell counts. By this mechanism of action, PLX-R18 could potentially treat a broad range of hematologic indications.

"The PLX-R18 product is designed to be an entirely new and innovative treatment approach for a wide variety of hematopoietic disorders, and might save the lives of severely ill patients with no alternative treatment options. We are encouraged by the strong pre-clinical data, and intend to pursue early market access in the U.S. for this important clinical indication," stated Pluristem Chairman and CEO, Zami Aberman.

Phase 1 Study Design

The planned study is a Phase 1, multi-center, open-label, dose-escalating study to evaluate the safety of intramuscular injections of PLX-R18 cells in subjects with incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). This study will be conducted in 30 subjects with incomplete hematopoietic recovery persistent for 6 months or more after HCT. There will be three cohorts: 1) 3 subjects receiving two administrations of 1 million PLX-R18 cells/kg

each, separated by a 1 week interval; 2) 12 subjects receiving two administrations of 2 million cells/kg each, separated by a 1 week interval; and 3) 15 subjects receiving two administrations of 4 million cells/kg each, separated by a 1 week interval. The follow up period will be 12 months. The primary endpoints will be safety endpoints and will include adverse events, laboratory values and vital signs. Exploratory endpoints will include changes in platelet and hemoglobin levels, changes in transfusion frequency, a shift from transfusion dependence to transfusion independence, quality of life and changes in the serum immunological parameters.

Bone Marrow Failure and HCT

Bone marrow failure is the inability of bone marrow to produce sufficient numbers of platelets, white or red blood cells. This inability may result in serious illness or death, because these cells are necessary to prevent hemorrhage, infection or severe anemia. Bone marrow failure can be caused either by medical conditions such as aplastic anemia, myelodysplastic syndrome, hematologic malignancies, or as a side effect of radiation or chemotherapy cancer treatment. The incidence of bone marrow failure resulting from these conditions varies widely, but is increasing.

The only cure for bone marrow failure is HCT, although supportive therapies and treatments can reduce symptoms and prolong life for some patients. The hematopoietic cells for HCT can come from a donor or from the patient, and can be harvested from peripheral blood, bone marrow or umbilical cord blood. Transplant patients require extensive care and monitoring, and sometimes need intensive treatment for complications. In cases of incomplete engraftment, blood cell counts are insufficient causing the patient to be at high risk of severe or lethal complications. In severe cases the patient may need to undergo the arduous and dangerous process of a second transplant.

About Pluristem Therapeutics

Pluristem Therapeutics is a leading developer of placenta-based cell therapy products. In 2016, the Company expects to initiate pivotal trials with PLX-PAD cells aimed at conditional marketing approval for the treatment of critical limb ischemia in Europe and Japan. A global Phase 2 trial is currently being conducted with PLX-PAD cells for the treatment of intermittent claudication. PLX cell products release product-specific cocktails of therapeutic proteins in response to conditions such as inflammation, ischemia or hematological disorders. The Company's proprietary, three-dimensional expansion technology can grow mass quantities of commercial-grade cells with batch-to-batch consistency at Pluristem's FDA and EMA-approved, state-of-the-art manufacturing facility. The cells are off-the-shelf, requiring no tissue matching prior to administration, making the treatment cost effective and readily available in virtually any medical setting. Pluristem has a strong intellectual property position and strategic relationships with major research institutions.

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 our expected Phase 1 trial of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT, including the recruitment process and its timing; when we discuss the possibility of PLX-R18, if successful, to be used to support the recovery of the hematological system and restore production of normal

levels of blood cells by the transplanted hematopoietic cells; when we discuss PLX-R18's potential to become novel innovative product with the ability to support the recovery of all three blood lines; when we discuss PLX-R18's potential to treat a broad range of indications related to abnormal bone marrow function; when we discuss the possibility of PLX-R18 cells to be an entirely new and innovative treatment for incomplete engraftment of HCT, and to save the lives of severely ill patients with no remaining treatment options; when we discuss our intention to pursue early market access in the U.S. for PLX-R18; and when we discuss our plan to initiate pivotal trials with PLX-PAD cells aimed at conditional marketing approval for the treatment of critical limb ischemia in Europe and Japan in 2016. 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. 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.