



Pluristem Advances its U.S. FDA Trial in Hematologic Indication

- *Enters into an agreement with a global drug development services company (CRO)*
- *Trial was cleared by U.S. FDA earlier this year*
- *Data could support use of Pluristem's PLX-R18 in a broad range hematologic indications*

HAIFA, ISRAEL, July 11, 2016 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced it has advanced its Phase I trial of PLX-R18 cells to treat insufficient hematopoietic recovery following hematopoietic cell transplantation (HCT) by contracting with a leading global clinical research organization (CRO).

The trial received clearance from the U.S. Food and Drug Administration earlier this year and enrollment is planned to begin in the coming months. The multi-center, open-label, dose-escalating Phase I trial will evaluate the safety of intramuscular injections of PLX-R18 cells in 30 patients with incomplete hematopoietic recovery persistent for 6 months or more after HCT.

“Data from this trial will inform the potential of PLX-R18 to treat a wide range of indications including blood cancers and radiation therapy-related blood diseases. The CRO we chose has extensive experience working with leading pharmaceutical and biotech companies to successfully manage clinical trials. We are excited to move forward to bring clinical sites online and begin enrolling patients,” said Pluristem Chairman and CEO Zami Aberman.

Data from multiple preclinical studies conducted by world-class research institutions, including the U.S. National Institutes of Health and Hadassah Medical Center, have shown that PLX-R18 cells secrete a range of specific proteins that support the regeneration of bone marrow and the recovery of its ability to produce normal amounts of all three blood cell types. PLX-R18 is designed to be administered without matching, and using a standard syringe to inject the cells intramuscularly.

Incomplete Recovery Following HCT

Hematopoietic cell transplantation 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, poor general function and death for months afterwards. 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 our [Phase I trial](#) of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT, its expected commencement, the data we expect to discover as a result of this trial. 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.