



Pluristem's PLX-R18 Advances into Second Cohort of Dose Selection Study for Treatment of Acute Radiation Syndrome

- *NIH's NIAID completes first cohort of dose selection study*
- *Data from completed study expected in first half of 2017*
- *Upon determining the optimal dose, a pivotal trial could be conducted to support marketing authorization of PLX-R18 for ARS under the FDA Animal Rule regulatory pathway.*

HAIFA, ISRAEL, December 6, 2016 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced a milestone in its development program for PLX-R18, which is being evaluated as a medical countermeasure in the treatment of the hematologic components of Acute Radiation Syndrome (ARS) by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH). ARS is caused by exposure to very high levels of radiation, such as could occur in a nuclear catastrophe. The syndrome can cause severe illness or death.

The U.S. Food and Drug Administration (FDA) previously advised Pluristem to conduct a pilot study in large animals to determine the optimal dosage of PLX-R18 as a treatment for the component of ARS that affects bone marrow function. The NIAID has now completed the dosing of the first cohort and is preparing to initiate dosing of the second and final cohort. Data from the completed study are expected in the first half of 2017. Based on these data the optimal treatment dose will be chosen for a pivotal large animal study designed to meet the requirements for a Biologics License Application (BLA) submission under the FDA's Animal Rule regulatory pathway.

The Animal Rule regulatory pathway allows for approval of treatments for diseases such as ARS in which human trials are not ethical or feasible. With this pathway, the FDA uses animal efficacy studies and human safety data as the basis for product approval.

"We are pleased with the advancement to the second cohort of the study that will determine the optimal dose of PLX-R18 in preparation for a pivotal trial. The support and collaboration of the NIH's NIAID have been instrumental in advancing PLX-R18 towards becoming an FDA-approved countermeasure ready for deployment in the case of a nuclear catastrophe," stated Pluristem Chairman and CEO Zami Aberman.

Previous NIH/NIAID studies of PLX-R18 in ARS

The NIAID has supported and completed two previous studies of PLX-R18, in which small animal models were used to evaluate the efficacy and mode of action of PLX-R18 as a potential treatment for the hematologic disorders associated with ARS. ARS involves severe, potentially lethal damage to the bone marrow's ability to produce blood cells and platelets, as well as to other systems and organs. Severe damage to bone marrow quickly makes victims vulnerable to life-threatening hemorrhage, infection and anemia. The more recent of the studies showed that intramuscular administration of PLX-R18 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, and described the treatment's mechanism of action. NIAID's initial studies of PLX-R18 showed a substantial, statistically significant improvement in 30-day survival and overall survival of irradiated rodents given PLX-R18 versus a control group.

About PLX-R18

PLX-R18 is Pluristem's second cell therapy product in development. It is designed to treat bone marrow that is unable to produce enough blood cells due to a variety of causes including ARS, certain cancers or cancer treatments, or immune-mediated bone marrow failure. Pluristem received FDA clearance to initiate a U.S. Phase I trial of PLX-R18 in incomplete bone marrow recovery following hematopoietic cell transplantation. Preclinical data from trials conducted by the NIH, 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. With its capabilities, PLX-R18 could potentially treat a broad range of hematologic indications, which together constitute a substantial global market.

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 cell products 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 initiation of the dosing of the second cohort by NIAID; when we discuss the timing of receiving the data from the completed study; when we discuss our plan to conduct a pivotal large animal study in order to submit a BLA under the FDA's Animal Rule regulatory pathway; when we discuss the possibility of approving

PLX-R18 by the FDA as a countermeasure in the case of a nuclear catastrophe; and when we discuss the potential of PLX-R18 to treat a broad range of hematologic indications, which together constitute a substantial global market. 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.

Contact:

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