Pluristem and U.S. Department of Defense Present Positive Data from Studies Testing PLX-R18 as a Prophylactic Treatment for Acute Radiation Syndrome

- PLX-R18 demonstrated significant increase in survival rates and recovery of the three blood lineages
- Data is jointly presented at the 2019 Radiation Injury Treatment Network (RITN) Workshop

HAIFA, Israel, July 31, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, is presenting positive results from a series of studies of the company’s PLX-R18 cell therapy product conducted by the U.S. Department of Defense’s (DoD) Armed Forces Radiobiology Research Institute at the Uniformed Services University of the Health Sciences. The studies were designed to evaluate PLX-R18 as a potential prophylactic countermeasure against acute radiation syndrome (ARS) administered prior to radiation exposure.

These animal studies demonstrate that PLX-R18, administered 24 hours before radiation exposure, and again 72 hours after exposure, resulted in a significant increase in survival rates, from 4% survival rate in the placebo group to 74% in the treated group. In addition, the data show an increase in recovery of blood lineages (platelets, neutrophils, white blood cells, and lymphocytes) and a favorable safety profile. Furthermore, histopathological analysis and hematopoietic progenitor clonogenic assay of tissues collected show a significant increase in bone marrow cell numbers and improved regenerative capability into all blood lineages.

“We are very pleased with the positive results from the studies showing that PLX-R18 can potentially be used prophylactically, before exposure to radiation. We believe that this outcome is an important contribution to protect the armed and medical forces which may need to enter contaminated areas,” said Yaky Yanay, President and Chief Executive Officer of Pluristem. “It is Pluristem’s goal to provide the different federal agencies access to PLX-R18 that it may be used as a countermeasure both before and after radiation exposure in order to minimize hematological and other organ damage. We look forward to the continued development of this unique agent as an off the shelf product.”

In addition to the DoD study, PLX-R18 is also being evaluated by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), as a treatment following radiation exposure (ARS). Data from these studies demonstrated a significant increase in survival rates and enhanced neutrophil and lymphocyte recovery in radiation subjects. PLX-
R18 cell therapy product candidate was granted an FDA orphan drug designation and an IND for the treatment of ARS.

The animal studies were conducted following guidance from the U.S. Food and Drug Administration (FDA) relating to its animal rule pathway.

About ARS
ARS results from exposure to high levels of radiation, as in the case of a nuclear accident or attack, and it may cause severe or fatal systemic effects such as injuries that hinder the bone marrow’s ability to produce blood cells and platelets, as well as other organs and systems within the body, increasing patients’ susceptibility to life-threatening hemorrhage, infection, and anemia.

About Pluristem Therapeutics
Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product and is currently conducting late stage clinical trials in several indications. PLX cell products release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; a Company-owned and operated GMP-certified manufacturing and research facility; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement
This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses the potential benefits of PLX-R18 and when it states that it believes the outcome of the studies is an important contribution to protect the armed and medical forces, that its goal is to provide the different federal agencies access to PLX-R18 so that it may be used as a countermeasure both before and after radiation exposure and that it looks forward to the development of PLX-R18 as an off the shelf product. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem’s products may not be approved by regulatory agencies, Pluristem’s technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key
employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem’s process; Pluristem’s products may wind up being more expensive than it anticipates; 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; Pluristem’s patents may not be sufficient; Pluristem’s products may harm recipients; changes in legislation may adversely impact Pluristem; 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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