Pluristem Therapeutics CEO Issues Shareholder Update

HAIFA, Israel, November 12, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today issued an update to its shareholders from its Chief Executive Officer, Yaky Yanay.

Dear Fellow Shareholders,

Today we announce Pluristem's update for the first fiscal quarter of 2020, as we are entering a very important period as we are in preparation towards the interim readout expected from our CLI phase III study. We continued to develop our robust clinical pipeline, with significant advancements in our hematological programs for PLX-R18 and PLX-PAD in the treatment of critical limb ischemia (CLI) and muscle regeneration.

PLX-R18, for the treatment of acute radiation syndrome (ARS), is advancing towards an important study with the potential for demonstrating the superiority of our cell therapy product versus the current standard of treatment, as we target governmental purchase contracts. We are preparing PLX-PAD, for the treatment of CLI, for potential conditional marketing approval in Europe, based on interim data we expect to receive in the second calendar quarter of 2020. We strongly believe, based on clinical data combined with our ability to manufacture large and consistent quantities of cell therapies, that Pluristem can heal and improve the lives of millions of patients while creating a new regenerative medicine model for healthcare.

I believe we have a significant upcoming value creating milestone in our ongoing Phase III CLI study. Interim data from this 246-patient study, which is being conducted in the U.S., Europe and Israel, is expected as mentioned in the calendric Q2 of 2020. Assuming the data from the study show good efficacy, we intend to submit an application to the European Medical Agency (EMA) for conditional marketing approval. We anticipate meeting with the EMA in order to confirm understanding towards the readout, as well as to set agreed process with our application for conditional marketing approval once positive data is reported. We are putting our resources and focus towards a commercialization event through discussions with payers regarding reimbursement, and with doctors and Key Opinion Leaders (KOLs) regarding integrating PLX-PAD as a standard of care treatment for CLI patients.

PLX-R18 has obtained Orphan Drug Designation in the U.S. for the treatment of ARS and for incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). We have been working in close partnership with various U.S. government agencies to develop PLX-R18 as a lifesaving treatment for victims exposed to high levels of radiation. During the last quarter, we reported positive data from the most recent studies conducted by the U.S. Department of Defense (DoD), which evaluated PLX-R18 as a prophylactic countermeasure against ARS, administered prior to radiation exposure. These animal studies, administering PLX-R18 24 hours before radiation exposure, and again 72 hours after exposure, resulted in a significant increase in survival rates, from a 4% survival rate in the placebo group to 74% in the treated group.

We have submitted a proposal to the Biomedical Advanced Research and Development Authority (BARDA) that is strategically designed to demonstrate the superiority of PLX-R18 versus current standards of care. KOLs in the ARS space have affirmed that despite the availability of several FDA approved countermeasures for ARS, there still remain significant treatment gaps. We believe that PLX-R18 is the best candidate to meet this need and that Pluristem can provide the U.S. government with effective countermeasures that can be easily stored, transported and deployed both pre-and post-exposure to military or civilian populations.

While the ARS studies are conducted under the FDA's animal rule pathway, PLX-R18 is also showing favorable results in clinical study for the treatment of HCT, a medical condition in which patients do not respond to current treatments. Pluristem's Phase I study of PLX-R18, conducted in the U.S. and Israel, has reported data from its first two cohorts, with the third and final cohort now in the process of enrolling and dosing. PLX-R18 appeared to regenerate damaged bone marrow, leading to increased production of platelets and red blood cells, ultimately reducing the number of required transfusions. While enrollment and treatment of the third cohort is ongoing, we seek to evaluate PLX-R18 as a candidate in additional bone marrow deficiency syndromes with similar unmet needs.

Pluristem is making significant momentum towards transitioning to the commercial, revenue generating stage of the Company. We appreciate and thank all of our shareholders for your support of Pluristem in its mission to improve healthcare through regenerative medicine.

Sincerely,
Yaky Yanay
Chief Executive Officer

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to 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 its preparation for PLX-PAD for the treatment of CLI for potential conditional marketing approval in Europe, the belief that it can heal and improve the lives of millions of patients while creating a new regenerative medicine model for healthcare, the belief that it has a significant upcoming value creating milestone in its ongoing Phase III CLI study, its intent to submit an application to the EMA for conditional marketing approval with respect to its ongoing Phase III CLI study, its anticipated meeting with the EMA in order to confirm understanding towards the readout, as well as to set agreed process with its application for conditional marketing approval with respect to its Phase III CLI study, its belief that PLX-R18 is the best candidate to fill the gap in treatment for ARS, its

seeking to evaluate PLX-R18 as a candidate in additional bone marrow deficiency syndromes with similar unmet needs and that it is making significant momentum towards transitioning to the commercial, revenue generating stage of the Company. 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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