Pluristem Therapeutics Recaps Key Opinion Leader Call Reviewing Hematological Programs

- *PLX-R18 is currently in development as a countermeasure for acute radiation syndrome and as a treatment for incomplete recovery following hematopoietic cell transplantation*
- *Data from 1st and 2nd cohorts of hematological study showed PLX-R18 was safe and well tolerated and led to increased production of platelets and red blood cells, ultimately reducing the number of required transfusions*
- *Yaky Yanay: "We have progressed our discussions with BARDA to submit a proposal by the end of September relating to an ARS study strategically designed to demonstrate the superiority of PLX-R18 versus current standards of care, with the goal of executing a full contract once the study is completed"*

HAIFA, Israel, September 16, 2019 - Pluristem Therapeutics Inc. **(Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing novel placenta-based cell therapy products, today provided a recap of the Key Opinion Leader call hosted by the company this morning to review unmet medical needs in acute radiation syndrome (ARS) and hematological deficiencies, and to provide an update on the development of its novel cell therapy treatment, PLX-R18. PLX cell therapy was granted an Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of ARS and incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT).

An overview of HCT was provided by Dr. Jacob M. Rowe, MD, Chief of the Department of Hematology and The Ann and Pinky Sohn Chair in Hemato-Oncology at the Shaare Zedek Medical Center in Jerusalem and Emeritus Professor at the Technion, Israel Institute of Technology in Haifa, a member in the company's ongoing hematology program steering committee. Dr. Rowe reviewed the medical condition of HCT and the unmet need for the significant proportion of patients that do not respond to current treatments. Dr. Rowe then discussed Pluristem's ongoing Phase I study of PLX-R18 and data from the first two cohorts:

- The study is comprised of 24 subjects in the U.S. and Israel. Cohort 3 (4 million cells/kg) is currently enrolling
- Data from 2 first cohorts, after a follow-up period of 6 month, have shown a median increase of platelets in cohort 1 (1 million cells/kg) and cohort 2 (2 million cells/kg) of 130% and 170%, respectively
- Median increase in hemoglobin levels in cohort 1 and cohort 2 was 34% and 36%, respectively
- A 65% reduction in platelet transfusion, and a 68% reduction in red blood cell transfusion, were observed compared to the last month before treatment in both cohorts
- A modest increase in neutrophil levels was seen in both cohorts

"Results from the first two cohorts in this study demonstrate that PLX-R18 is safe and well tolerated, with no unexpected toxicities," said Dr. Rowe. "While the study's primary endpoint was safety, we can't disregard the potential benefits of this cell therapy drug, which even in the lower doses appears to

regenerate damaged bone marrow, leading to increased production of platelets and red blood cells, ultimately reducing the number of required transfusions, although caution is appropriate in discussing early data with a small number of patients. Importantly, we see these positive benefits sustained at the nine months follow-up period, and we continue to monitor these patients. We look forward to results from Cohort 3, in which patients will be administered four million cells per kilogram, as we work to efficiently advance PLX-R18 as a candidate in additional bone marrow deficiency syndromes with similar unmet needs."

The next presentation was delivered by Bert W. Maidment, Ph.D., who served as Assistant Director, Radiation Nuclear Countermeasures Program at the National Institutes of Health, National Institute of Allergy and Infectious Diseases, Division of Allergy, Immunology, and Transplantation (NIH/NIAID/DAIT) until retiring in 2016. Dr. Maidment discussed the health impact of radiation exposure and the need for more effective countermeasures. "There is a broad range of devastating health consequences resulting from radiation exposure, with hematopoietic, gastrointestinal, cardiovascular and central nervous systems all potentially impacted," noted Dr. Maidment. "Notwithstanding several FDA-approved countermeasures, including Neupogen®, Neulasta® and Leukine®, significant treatment gaps remain, causing widespread manifestations across vital organ systems. I believe that a more efficacious countermeasure that can be administered pre- and post-exposure, particularly one that is easily stored and administered and potentially support multiple organ injuries, would have significant utility across a number of civilian and military applications where radiation exposure is a potential risk."

Pluristem management provided an overview of the company's acute radiation syndrome (ARS) projects that are running with several governments and agencies, including the U.S. National Institutes of Health (NIH), testing PLX-R18 as a potential treatment for ARS, the U.S. Department of Defense (DOD) testing the product as a potential prophylactic countermeasure against ARS and Fukushima University in Japan examining PLX-R18 cells for the treatment of hematological ARS and gastrointestinal (GI). Arik Eisenkraft, Director of Homeland Defense Projects at Pluristem and former Head of Chemical, Biological, Radiological and Nuclear Defense (CBRN) Protection Division in the Israeli Ministry of Defense, summarized PLX-R18's potential to stimulate the regeneration of damaged bone marrow to produce blood cells while also increasing survival and benefiting additional body systems, suggesting that PLX-R18 has the ability to treat ARS as a multi-organ therapy.

Yaky Yanay, Chief Executive Officer of Pluristem, concluded the call with an update on the status of current projects and provided an overview of next steps. "I would like to thank Drs. Rowe and Maidment for offering their perspectives on these difficult-to-treat hematological conditions. We look forward to advancing our ARS program to complete the development and registration of PLX-R18 for ARS, targeting governmental purchase contracts.

1. After reaching an understanding with the FDA on the regulatory pathway needed and conducted additional mechanism studies with the support of the NIH, we have progressed our discussions with the Biomedical Advanced Research and Development Authority (BARDA) to submit a proposal by the end of September, aiming for a study, strategically designed to demonstrate the superiority of PLX-R18 versus current standards of care, with the goal of executing a full contract once the study is completed.
2. Following the studies conducted by the U.S. Department of Defense, we are now progressing to further small and large animal studies in relevant DoD models, as required by the FDA animal rule pathway.

We remain committed to completing our ongoing Phase I study of PLX-R18 in incomplete hematopoietic recovery following HCT as quickly as possible and will seek to expand PLX-R18 for use with respect to

additional medical conditions with the goal of bringing innovative, safe and effective treatments for patients with a variety of bone marrow deficiency indications."

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 the potential benefits of PLX-R18 as identified in the study, the potential use of PLX-R18 in civilian and military applications where radiation exposure is a potential risk, that PLX-R18 has the ability to treat ARS as a multi-organ therapy, the advancement of its ARS program to ultimately target governmental purchase contracts, its progress with respect to small and large animal studies in relevant DoD models, as required by the FDA animal rule pathway, its aim to submit a proposal by the end of September with respect to BARDA, with the hopes of commencing a study designed to demonstrate the superiority of PLX-R18 in the treatment of ARS versus current standards of care and with the goal of executing a full contract once the study is completed and its aim to expand the focus of PLX-R18 to additional medical conditions with the goal of bringing innovative, safe and effective treatments for patients with a variety of bone marrow deficiency indications. 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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