Pluristem Concludes Positive Meeting with FDA on Development Plan for Acute Radiation Syndrome

Meeting included representatives from NIH and BARDA

HAIFA, Israel, January 3, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced it has concluded a positive meeting with the U.S. Food and Drug Administration (FDA) regarding the ongoing development of PLX-R18 for the treatment of Acute Radiation Syndrome (ARS). The FDA provided Pluristem with feedback on the progress and data collected on PLX-R18 to date and gave guidance towards advancing the development of PLX-R18 with respect to the treatment of ARS. The meeting also included representatives from the U.S. National Institute of Allergy and Infectious Diseases (NIAID) and the U.S. Biomedical Advanced Research and Development Authority (BARDA).

"We are pleased to have completed a positive meeting with the FDA and U.S. government agencies representatives, which we believe has provided us with a clear and efficient path towards advancing the development of PLX-R18, targeting approval in the treatment of ARS," said Mr. Yaky Yanay, Co-Chief Executive Officer and President of Pluristem. "For several years, we have successfully cooperated with the NIAID, which has supported and conducted studies of PLX-R18 in ARS. These studies demonstrated PLX-R18 potential to increase survival rates after radiation exposure, as well as protect and regenerate the bone marrow's ability to produce blood cells, crucial for victims exposed to high levels of radiation. We are pleased to see interest from key governmental agencies such as NIAID, the U.S Department of Defense and BARDA in our novel regenerative medical countermeasure for radiation injuries and look forward to potentially supporting such medical needs of the U.S. government."

PLX-R18 has been studied in Phase I and II-equivalent studies conducted and funded by NIAID via the FDA Animal Rule Pathway. Results from these studies showed that PLX-R18 supports the recovery of the bone marrow and increases survival rates. PLX-R18 has been granted an Investigational New Drug application (IND) and an orphan drug designation by the FDA for the treatment of ARS.

ARS involves severe, potentially lethal damage to the bone marrow's ability to produce blood cells, as well as to other systems and organs. Severe damage to bone marrow renders victims vulnerable 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 cells and is entering late stage 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; 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 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 states its belief that, as a result of its meeting with the FDA, it has a clear and efficient path towards advancing the development of PLX-R18 in the treatment of ARS and its potential support of the U.S. government with respect to its medical needs relating to radiation injuries. 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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