# FDA Grants Pluristem Orphan Drug Designation for Its PLX-R18 Cell Therapy as Treatment for Acute Radiation Syndrome

*Pluristem's ARS program is developed and funded by the U.S. National Institutes of Health and the U.S. Department of Defense, and is in preparation for a pivotal study*

***HAIFA, ISRAEL, October 19, 2017***-- Pluristem Therapeutics Inc. (NASDAQ: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. Food and Drug Administration (FDA) has granted the company an orphan drug designation for its PLX-R18 cell therapy for the prevention and treatment of acute radiation syndrome (ARS).

ARS results from exposure to high levels of radiation, such as in the case of a nuclear accident or attack, and can lead to severe health consequences including death. The Orphan Drug Act provides for granting special status to a drug or biological product, to treat a rare disease or condition. The benefits of achieving Orphan Drug Designation include close guidance by the FDA, which may accelerate the path to potential marketing approval, orphan drug grants, tax credits, and 7-year market exclusivity upon marketing approval.

Pluristem recently reported positive data from non-human primates (NHPs) studies of PLX-R18 cells as a treatment for ARS conducted by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), U.S. Department of Health and Human Services (DHHS). The reported data demonstrated improvement in survival rates of such NHPs and the enhancement of recovery across all three major blood lineages—white blood cells, red blood cells, and platelets. In addition, PLX-R18 cells are also being studied by the U.S. Department of Defense's (DOD) Armed Forces Radiobiology Research Institute (AFRRI) to examine the effectiveness of the cells as a treatment for ARS prior to, and within the first 24 hours of exposure to radiation. Pluristem PLX-R18 cells are also being studied by Fukushima Medical University in Japan for the treatment of ARS and as an adjunct to radiotherapy in cancer patients.

"Pluristem has a vast and dynamic program developing our PLX-R18 therapy as a treatment for ARS, which can potentially save many lives," said Zami Aberman, Co-CEO and Chairman of Pluristem. "Receiving Orphan Drug Designation brings us one step closer to providing a next-generation medical countermeasure against ARS, which is especially important given today's volatile political climate."

**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 acute radiation syndrome (ARS), certain cancers or cancer treatments, or immune-mediated bone marrow failure. PLX-R18's first animal studies in ARS were performed in collaboration with Prof. Gorodetsky at Hadassah Medical Center. Further preclinical data from trials conducted by the U.S. National Institutes of Health, Hadassah, the Charite in Berlin 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. Pluristem is currently enrolling patients in a U.S. Phase I trial of PLX-R18 in incomplete bone marrow recovery following hematopoietic cell transplantation (HCT) and is preparing for a pivotal trial in ARS.

**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, 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, we are using forward-looking statements when we discuss developing our PLX-R18 therapy as a treatment for ARS, which can potentially save many lives, or when we discuss the benefits of receiving Orphan Drug Designation for our PLX-R18 therapy and that it brings us one step closer to providing a next-generation medical countermeasure against ARS. 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

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