Pluristem and NIAID Met with U.S. FDA and Agreed on Development Plan for Initiation of Pivotal Study of PLX-R18 in the Treatment of Acute Radiation Syndrome

PLX-R18 for use in Acute Radiation Syndrome (ARS) is being developed under the Animal Rule regulatory pathway with the NIAID's support

HAIFA, ISRAEL, September 21, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that Pluristem and the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), completed a successful meeting with the U.S. Food and Drug Administration (FDA) regarding the development program for PLX-R18 cells in the treatment of Acute Radiation Syndrome (ARS). ARS is caused by exposure to dangerously high levels of radiation, such as those that could occur in a nuclear catastrophe. The FDA communicated that the data presented at the meeting allow for the design of large animal studies, which are the only studies required to prove efficacy for FDA approval under the Animal Rule; this is the regulatory pathway followed when human efficacy trials are not ethical or feasible. The FDA also offered to assist Pluristem with the design of these trials. The NIAID, which has supported and conducted two earlier studies of PLX-R18 in a mouse model of ARS, communicated its interest in supporting and completing trials in large animals as well, pending protocol review by the FDA.

The FDA advised Pluristem to conduct a pilot study in large animals to determine the optimal dose of PLX-R18 as a treatment for the hematologic component of ARS. Once the optimal dose schedule is determined, a pivotal trial in large animals could commence. If successful, this trial would provide sufficient efficacy data for an application to the FDA for approval of PLX-R18 as a treatment for ARS.

"This positive meeting with the FDA is a major step forward for our PLX-R18 program, and we expect to submit a protocol to the FDA for the dosing trial in large animals as soon as possible," said Pluristem Chair and CEO Zami Aberman. "FDA approval of PLX-R18 for ARS could generate U.S. government interest in stockpiling it for use in the case of a nuclear disaster, since PLX cell products are ideally suited for rapid initiation of treatment of large populations. Our cells do not require tissue matching prior to administration and can be administered quickly via intramuscular injection." Mr. Aberman added, "We value our close working relationship with the NIH/NIAID, and look forward to continuing to collaborate with them."

Previous NIH/NIAID studies of PLX-R18 in ARS

The NIH has supported and completed two mouse studies of PLX-R18 as a potential treatment of the component of ARS that affects bone marrow function. ARS involves severe, potentially lethal damage to the bone marrow's ability to produce blood cells and platelets, as well as to other systems and organs. Severe damage to bone marrow quickly makes victims vulnerable to life-threatening hemorrhage, infection and anemia. A recently concluded NIH/NIAID study showed that administration of PLX-R18 resulted in a statistically significant improvement in the recovery of white blood cell, red blood cell, and platelet levels in animals exposed to high levels of radiation, and described the cells' mechanism of action. The NIH/NIAID's first study of PLX-R18 showed a substantial, statistically significant improvement in 30-day survival and overall survival of irradiated rodents given PLX-R18 versus a control.

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 blood cells due to a variety of causes including ARS, certain cancers, or immune-mediated bone marrow failure. Pluristem is preparing to initiate a Phase I trial of PLX-R18 in incomplete bone marrow recovery following hematopoietic cell transplantation. With its capabilities, PLX-R18 could potentially treat a broad range of indications related to bone marrow function, which together constitute a substantial global market.

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. The cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has: a strong intellectual property position; company-owned, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws For example, we are using forward-looking statements when we discuss the expected timing for submitting a protocol to the FDA for the dosing trial of PLX-R18 in large animals, when we discuss potential U.S. government interest in stockpiling our PLX-R18 for use in the case of a nuclear disaster, when we discus initiating a Phase I

trial of PLX-R18, when we discuss PLX-R18's potential to treat a broad range of indications related to bone marrow function, and when we discuss PLX-R18's potential substantial global market. 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; 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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