



## **Pluristem Announces Promising Results from Non-Human Primate Pilot Study of PLX-R18 in Acute Radiation Syndrome**

- *All PLX-treated groups showed improvements in survival rates compared to untreated groups*
- *PLX-R18 cells did not increase leukocyte levels in non-irradiated NHPs, indicating no requirement to determine levels of radiation exposure prior to administration*
- *Data will inform a pivotal trial that could support marketing authorization under the FDA's Animal Rule regulatory pathway*

**HAIFA, ISRAEL, May 3, 2017**— [Pluristem Therapeutics Inc.](#) (NASDAQ: PSTI), (TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today the promising results of its non-human primates (NHP) pilot study for PLX-R18 as a treatment for Acute Radiation Syndrome (ARS). The study, conducted and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), was designed to assess the safety and efficacy of PLX-R18 following intramuscular injection into irradiated and non-irradiated NHPs. Efficacy measures included survival as well as level of bone marrow function, which is affected by exposure to high levels of radiation as may occur in a nuclear accident or attack.

While this pilot study was not powered to demonstrate statistical significance, all cohorts treated with PLX-R18 showed improved survival compared to cohorts that received placebo. The two lower dosages, 4 and 10 million cells per kilogram body weight, resulted in an 85% survival rate in irradiated NHPs compared to a 50% survival rate in the placebo treated control group. This pilot study also demonstrated a trend towards enhanced neutrophil and lymphocyte recovery.

No serious adverse reactions were observed in non-irradiated NHPs, suggesting that in scenarios requiring the rapid treatment of large populations, such as in the case of a nuclear emergency, no determination of an individual's level of exposure would be required prior to treatment.

These data will help inform a pivotal study designed to meet the requirements for a Biologics License Application (BLA) submission under the FDA's Animal Rule regulatory pathway.

"These findings are in line with what we've seen in previous studies and strengthen our commitment to delivering a ready-to-use treatment to counteract the devastating effects of ARS," said Zami Aberman, Co-CEO and Chairman of Pluristem.

"The transition from small to large animals has always been a challenge in therapeutic product development, and the success of this study marks a significant milestone. Our unique, multifactorial PLX-R18 cell therapy was developed to repair the body's ability to produce all three blood lineages in a timely manner. This therapy would protect patients from severe infection, anemia and hemorrhage, saving lives in the case of a nuclear event. We are pleased that these findings support this treatment's efficacy and are looking forward to results from further studies," added Aberman.

"Following this successful trial, we look forward to continuing our discussions with U.S. government agencies regarding continued support for a pivotal trial" said Yaky Yanay, Co-CEO and President of Pluristem. "We are confident that PLX-R18 can serve as a powerful tool for governments to protect their citizens against the devastating health impact of potential exposure to nuclear radiation. We are proud to have developed a treatment that could save many lives."

### **About ARS**

Acute Radiation Syndrome occurs following acute exposure to very high levels of radiation, and involves severe, potentially lethal injury to the bone marrow as well as to other organs and systems within the body. High doses of radiation can destroy the bone marrow's ability to produce white cells, red cells and platelets; without these cells patients are at high risk of death.

### **About the pilot study**

The objective of the study was to evaluate survival and hematology parameters as well as safety parameters in irradiated (target LD30/45) and non-irradiated male and female NHPs (total 48 animals), following intramuscular treatment with 3 doses (4.0, 10.0 and 20.0 million cells per Kg) of PLX-R18 as compared to non-treated controls.

### **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 ARS, certain cancers or cancer treatments, or immune-mediated bone marrow failure. Pluristem received FDA clearance to initiate a U.S. Phase I trial of PLX-R18 in

incomplete bone marrow recovery following hematopoietic cell transplantation. Preclinical data from trials conducted by the NIH, Hadassah Medical Center, 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. With its capabilities, PLX-R18 could potentially treat a broad range of hematologic indications, 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 and is entering late-stage trials in several indications. The cell products release a range 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 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 Pluristem's belief that the data from the NHP pilot study of PLX-R18 will pave the way for a pivotal study designed to meet the requirements for a BLA submission under the FDA's Animal Rule regulatory pathway, Pluristem's discussions with U.S. government agencies regarding continued support for a pivotal trial and Pluristem's confidence that PLX-R18 can serve as a powerful tool for governments to protect their citizens against the devastating health impact of potential exposure to nuclear radiation. 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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