



## **U.S. Department of Defense to Conduct Studies of Pluristem’s PLX-R18 in a New ARS Project for Use Before Radiation Exposure**

- *The DOD studies seek to test the effectiveness of PLX-R18 as a novel medical countermeasure for Acute Radiation Syndrome (ARS) prior to and within 24 hours of exposure to high levels of radiation*
- *The DOD studies will be conducted in parallel with the ongoing ARS project with the NIH*

**HAIFA, ISRAEL, August 16, 2017**— [Pluristem Therapeutics Inc.](#) (NASDAQ: PSTI) (TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that a pilot study of the company’s PLX-R18 cell therapy will be initiated by the U.S. Department of Defense’s (DOD) Armed Forces Radiobiology Research Institute (AFRRI), part of the Uniformed Services University of Health Sciences (USU). The study will examine the effectiveness of PLX-R18 as a treatment for Acute Radiation Syndrome (ARS) prior to, and within the first 24 hours of exposure to radiation.

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. Pluristem [recently reported](#) positive data from 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). Data demonstrated improvement in survival rates and enhancement of blood lineages recovery.

A key difference in the NIAID study and the upcoming DOD study is the timeframe of exposure that is being examined: in the NIAID study, PLX-R18 was administered to subjects 24 hours post exposure, while the new DOD study will be designed to support the needs of the U.S. Armed Forces and examine subjects receiving treatment prior to, or within the first 24 hours of radiation exposure. The DOD studies will be conducted in parallel with the NIH/DHHS studies, allowing broader understanding of the potential therapeutic effects of PLX-R18 as a novel medical countermeasure for ARS.

The study will be conducted in accordance with the FDA Animal Rule pathway, the regulatory pathway followed when human efficacy trials are not feasible, in this case due to the ethics of exposing humans to nuclear radiation. Product approval via this pathway is granted following large animal efficacy studies and human safety data.

“We are pleased to see increased interest from US governmental agencies in our PLX-R18 cell therapy,” noted Zami Aberman, Chairman and Co-CEO of Pluristem. “In view of the therapeutic effects of our product and the current geopolitical situation, governments can potentially shield their citizens from the dire health effects arising from exposure to nuclear radiation, saving many lives in the process, which is our ultimate goal.”

## **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.

## **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 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.

## **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 how the proposed DOD study will be conducted and the various phases of the study, as well as when we discuss that governments can potentially shield their citizens from the dire health effects arising from exposure to nuclear radiation, saving many lives in the process, while using our products. 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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