



## **National Institutes of Health's NIAID Initiating Dose Evaluation Studies in Animal Models of Pluristem's PLX-R18 in the Treatment of Acute Radiation Syndrome**

*Second Hematologic Indication Being Developed in the U.S. for PLX-R18*

**HAIFA, ISRAEL, February 16, 2016 --** [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced that the National Institute of Allergy and Infectious Diseases (NIAID), a part of the U.S. National Institutes of Health (NIH), will initiate studies in large animals to evaluate dosing for Pluristem's PLX-R18 as a medical counter measure in the treatment of the hematologic components of Acute Radiation Syndrome (ARS). Once the optimal dose is determined in large animals, a pivotal trial could be conducted and the results used to support a Biologics License Application (BLA) submission of PLX-R18 for this indication under the Animal Rule regulatory pathway. In September 2015, the FDA had confirmed that data from earlier trials conducted by NIAID were sufficient for the future design of studies in Pluristem's development path for PLX-R18. NIAID is supporting and collaborating on the dosing studies, and Pluristem is supplying PLX-R18.

ARS is caused by exposure to very high levels of radiation, such as those that could occur in a nuclear catastrophe. The syndrome can cause severe illness or death. When human trials are not ethical or feasible, as in this indication, the FDA's Animal Rule regulatory pathway allows for the determination of the efficacy of drugs using animal efficacy studies and human safety data.

"We are very pleased to receive the support and collaboration of the NIH for the development of PLX-R18 as a medical countermeasure in the treatment of ARS, which is the first indication we are targeting in the defense technology space," stated Pluristem Chairman and CEO Zami Aberman.

Pluristem recently received FDA clearance to initiate a Phase I trial of PLX-R18 to treat incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT). This trial is scheduled to begin in the first half of 2016 in the U.S. Additionally, Pluristem has entered into a Memorandum of Understanding (MOU) with Japan's Fukushima Medical University, Fukushima Global Medical Science Center to develop PLX-R18 for the treatment of ARS and for morbidities following radiotherapy in cancer patients.

## **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 treatment's 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 group.

## **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 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 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 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 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 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 NIAID study, continued support of the NIH, when we discuss the results of the study and its potential use to apply for marketing authorization PLX-R18, the possibility to use results of the study in question to conduct a pivotal study and facilitating the development of PLX-R18 in other hematologic indications, when we discuss our plan to begin a Phase I trial to treat incomplete hematopoietic recovery following HCT in the first half of 2016, and when we discuss PLX-R18's potential to treat a broad range of hematologic indications, which together constitute a 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; 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. 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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