



Pluristem and Indiana University to Initiate Joint Project Evaluating PLX-R18 in Acute Radiation Syndrome, Targeting Bridging Data for Pivotal Study

- *The 5-year joint project was granted \$2.5 million from the U.S. National Institutes of Health (NIH)*
- *Data from these studies will support BLA filing for marketing approval of PLX-R18 in the treatment of ARS*

HAIFA, Israel, April 23, 2018 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has awarded a \$2.5 million grant to Indiana University to conduct studies of Pluristem's PLX-R18 cell therapy in the treatment of acute radiation syndrome (ARS).

The goal of this project is to extend the PLX-R18 ARS studies to include examination of survival efficacy in additional populations, such as geriatric and pediatric, and to compare the effectiveness and examine interactions with other drugs, such as Granulocyte-Colony Stimulating Factor (G-CSF). Data collected during the first year of this 5-year research agreement will support Pluristem's Biologics License Application (BLA) filing with the U.S. Food and Drug Administration (FDA) for marketing approval of PLX-R18 in the treatment of ARS.

The \$2.5 million, 5-year research collaboration agreement will be performed in conjunction with Indiana University researchers led by Prof. Christie M. Orschell. As part of this agreement, Pluristem will be reimbursed for supplying PLX-R18 cells for these studies.

Following previous positive results from a Phase II-equivalent study in non-human primates, sponsored by NIAID, Pluristem is now in discussions with the FDA and several U.S. governmental agencies to clear the path and funding for a pivotal study of PLX-R18 in the treatment of ARS.

"We are very pleased to receive NIH support through this important grant to Indiana University for advancing PLX-R18 towards becoming an approved countermeasure for ARS. Pluristem looks forward to working with the researchers at Indiana University who have broad expertise in this field of research," stated Pluristem Co-CEO and President Yaky Yanay. "We expect to collect data from these studies to support the initiation of the pivotal study protocol, an essential step in the PLX-R18 product development."

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 and is entering late-stage trials in several indications. Our 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, Pluristem is using forward-looking statements when it discusses collaboration with Indiana University, allocation of grants, reimbursement to Pluristem for supplying PLX-R18 cells for the studies conducted with Indiana University, discussions with the FDA and governmental agencies to clear the path and funding for a pivotal study of PLX-R18, that data collected from the studies will support the initiation of a pivotal study protocol and Pluristem's BLA with the FDA for marketing approval of PLX-R18. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; 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; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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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