



U.S. FDA Clears Pluristem's IND to Treat Victims Exposed to Acute Radiation

HAIFA, Israel, April 30, 2018 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for its PLX-R18 cell therapy in the treatment of acute radiation syndrome ([ARS](#)). The IND allows Pluristem to treat victims who may have been acutely exposed to high dose radiation due to nuclear attack or accident. With this IND in place, Pluristem will now start the necessary preparations in order to keep an emergency stock of PLX-R18 on hand for use in such events.

The U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIAID) sponsored and completed a successful Phase II-equivalent study of PLX-R18 in the treatment of ARS via the FDA's animal rule pathway. PLX-R18 is also being studied by the U.S. Department of Defense (DOD) to support the needs of the armed forces and study PLX-R18 as a treatment prior to, or within the first 24 hours of, radiation exposure. Pluristem is currently in discussions with the FDA and several U.S. governmental agencies to clear the path for its proposed pivotal study of PLX-R18 in ARS.

Per the IND protocol, PLX-R18 will be provided up to 96 hours following radiation exposure. The approved dosage for treatment in humans is 4 million cells per kilogram, the optimal dosage that was determined in the Phase II-equivalent non-human primate pilot study. PLX-R18 cells demonstrated a dramatic increase in survival of population exposed to high dose of radiation and enhancement of blood lineages recovery.

"We are proud to have PLX-R18 join the exclusive club of IND approved medical countermeasures for the treatment of ARS. This FDA clearance is one of the most significant milestones in the development of PLX-R18 to date and should provide Pluristem with significant support in advancing its off-the-shelf cell therapy into a pivotal trial. The fact that we are now able to treat human casualties in the case of a nuclear event provides us with the ability to protect from severe health consequences, saving lives of population in need," stated Pluristem Chairman and Co-CEO Zami Aberman.

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 blood cells, red blood cells and platelets; without these cells patients are at high risk of death.

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. PLX-R18's first animal studies in ARS were performed in collaboration with Prof. Gorodetsky at Hadassah Medical Center. Further preclinical data from trials conducted by the U.S. National Institutes of Health, Hadassah, the Charité in Berlin and other prominent research institutions, have shown that PLX-R18 cells secrete a range of specific proteins that salvage and trigger the regeneration of bone marrow hematopoietic cells, thereby supporting the recovery of blood cell production. With its capabilities, PLX-R18 could potentially be used in several indications to treat a broad range of hematologic disorders, which together constitute a substantial global market. Pluristem is currently enrolling patients in a multinational Phase I trial of PLX-R18 in incomplete bone marrow recovery following hematopoietic cell transplantation.

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 following intramuscular administration, 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 its intention to keep an emergency stock of PLX-R18 on hand for use in a nuclear event, its proposed pivotal study of PLX-R18 in ARS, its belief that the approved IND may provide it with the potential to help populations in need as well as support its ARS program and its belief that the IND approval will provide it with significant support in advancing its off-the-shelf cell therapy into a pivotal trial. 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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