New Data from ARS Study Shows Significant Hematological Deficiencies Even at Low Radiation Levels; PLX-R18 Supports Hematological Recovery

- Findings pave the way to potentially use PLX-R18 to support hematological recovery following radiotherapy or chemotherapy
- Data focuses on 12 additional NHPs that were exposed to lower radiation levels

HAIFA, ISRAEL, JULY 26, 2017 — Pluristem Therapeutics Inc. (NASDAQ: PSTI) (TASE: PSTI), a leading developer of placenta-based cell therapy products, today presented new data at the RITN (Radiation Injury Treatment Network) conference from a recent study evaluating PLX-R18 as a treatment for Acute Radiation Syndrome (ARS).

Pluristem recently announced positive data from a Phase II-equivalent study under the FDA Animal Rule demonstrating improved survival and hematological recovery of non-human primates (NHP) exposed to high levels of radiation. The study was conducted and funded by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH).

New data from the study focuses on 12 additional NHPs that were exposed to lower radiation levels than those in the initial study. In a radioactive or nuclear incident, many victims will suffer from health effects resulting from low radiation exposure and not necessarily from the more dire impact of exposure to high radiation levels. The findings suggest that even though low radiation exposure is not lethal, it can lead to serious hematological deficiencies and to long-term health problems that result from such damage.

Neutrophil, lymphocyte, and platelet counts of the 12 PLX-R18-treated subjects showed faster recovery than those of the study’s control group. This finding indicates that PLX-R18 could potentially be used as a treatment for additional indications relating to bone marrow deficiencies, such as those that may occur due to radiotherapy, chemotherapy, adverse drug reaction and some genetic conditions.

These new findings also strengthen the safety profile of PLX-R18 in subjects exposed to different levels of radiation and even to subjects not exposed to radiation at all. This is a critical factor in case of disasters where screening of victims for exposure levels would delay treatment and potentially reduce its efficacy.

In addition, a thorough analysis of the initial group of 24 NHPs exposed to high doses of ionizing radiation showed that PLX-R18 treatment shortened the length of time spent below severe blood count thresholds, thus avoiding serious infections, hemorrhaging, and anemia.
“There is a crucial need for a therapy to effectively treat populations in case of nuclear or radioactive incidents. These positive results strengthen our confidence in the safety profile and treatment potential of PLX-R18 for different levels of radiation exposure. These new findings, showing improvement in the hematologic system at lower radiation levels, suggest that PLX-R18 has the potential to treat the broader population exposed to different levels of radiation and might also be used for additional indications such as mitigating the negative effects of cancer treatments like chemotherapy,” said Yaky Yanay, president and Co-CEO of Pluristem. “With the knowledge that applications of PLX-R18 could go far beyond treating victims of nuclear incidents, we are one step closer to fulfilling our goal of providing better treatment options for millions of patients worldwide.”

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 that the findings of the PLX-R18 study indicate the potential for PLX-R18 to be used as a treatment for additional indications and to be effective in treating radiation exposure, as well as when we discuss that the findings of the PLX-R18 study strengthens the safety profile of PLX-R18 administered to subjects exposed to different levels of radiation or even to subjects not exposed to radiation at all. 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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