Pluristem Therapeutics Announces Completion of 2nd Cohort and DSMB Approval to Enroll Final Cohort in Phase I Hematological Study of PLX-R18

Findings from first two cohorts show primary safety endpoint met and early signals of efficacy

HAIFA, Israel, March 12, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that the Company has fully enrolled the second cohort of six patients in its ongoing Phase I clinical study evaluating PLX-R18 for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT), and has received Data and Safety Monitoring Board (DSMB) approval to continue to the final cohort of the study.

Results from the first two cohorts demonstrate PLX-R18 is safe and well tolerated, with early signals of efficacy in improving blood counts. The third and final cohort will be comprised of 15 patients that will receive two administrations of four million PLX-R18 cells/kg, one week apart, considered as the target dose for these patients.

"We are highly encouraged by the findings from the first two cohorts in this study, and we are pleased to receive DSMB approval to continue with the study as planned, as we look to efficiently advance PLX-R18 through clinical development," commented Zami Aberman, Chairman and Co-Chief Executive Officer of Pluristem. "Incomplete hematopoietic recovery poses a significant risk to HCT recipients who fail to respond to the usual standards of care, making them vulnerable to severe complications and potentially resulting in their incurring significant related costs. We believe PLX-R18 can address the unmet need in this patient population by reviving the regenerative potential of the bone marrow and blood cell growth where other treatments have proven ineffective, and we look forward to final results from this study."

About the study

This Phase I study is designed as a multi-center, open-label, dose-escalating study to evaluate the safety of intra-muscular (IM) injections of PLX-R18 cells in 24 patients with incomplete hematopoietic recovery persisting for at least four months after HCT. The follow up period for safety is 12 months. Patients in the study are enrolled into three chronological treatment groups: two administrations of 1 million PLX-R18 cells/kg (n=3), two administrations of 2 million PLX-R18 cells/kg (n=6) and two administrations of 4 million PLX-R18 cells/kg (n=15). The primary endpoint is safety which is assessed, at the end of each cohort, by an external DSMB. In addition, exploratory evaluations are made, including changes in platelet and hemoglobin levels, changes

in transfusion frequency, a shift from transfusion dependence to transfusion independence, changes in quality of life and changes in the serum immunological parameters.

PLX-R18 cell therapy for the treatment of incomplete hematopoietic recovery following HCT was granted Orphan Drug Designation by the U.S. Food and Drug Administration.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical study data in multiple indications for its patented PLX cells and is entering late stage clinical studies in several indications. PLX cell product candidates are believed to 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; a Company-owned and operated, GMP-certified manufacturing and research facility; 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 the proposed final cohort of its Phase I study and the belief that PLX-R18 can revive the regenerative potential of the bone marrow and blood cell growth in patients suffering from incomplete hematopoietic recovery. 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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