



## **Pluristem Presents Data from First Cohort in Ongoing Phase I Hematological Study at the American Society of Hematology (ASH) Annual Meeting**

- **Primary safety endpoint met in first cohort with early signals of efficacy in improving blood counts**
- **Trial is progressing with enrollment in the second cohort currently underway**

**HAIFA, Israel, December 3, 2018** - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that the Company presented data from the first cohort of patients in its ongoing Phase I clinical trial of PLX-R18 for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT) at the American Society of Hematology (ASH) 60<sup>th</sup> Annual Meeting and Exposition, which is being held December 1-4 in San Diego.

The poster, titled "Prospective, Multi-Center, Phase I Clinical Trial of PLX-R18 Placental Expanded Adherent Stromal Cells in Subjects with Incomplete Hematopoietic Recovery after Hematopoietic Cell Transplantation," summarizes findings from the first cohort of three patients in the Company's Phase I clinical study which is ongoing in the U.S. and Israel. Patients were administered two doses of PLX-R18 one week apart via intramuscular (IM) injections at the lowest of three doses to be evaluated (1 million PLX-R18 cells/kg). The treatment was found to be safe and well tolerated, with no unexpected toxicities. All safety data had been reviewed by an external safety committee and based on the safety presented to them study was approved to move forward. In addition, early signals of efficacy in improving blood counts were observed. As previously announced in September 2018, the 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.

"We are pleased that the first cohort in this important study met its primary objective of safety, and are encouraged by the early signals of efficacy that we observed, even at the lowest dose in patients suffering from serious hematological condition failing to reach hematopoietic recovery," commented Zami Aberman, Chairman and Co-Chief Executive Officer of Pluristem. "We are now enrolling the second cohort of patients to be evaluated at an intermediate dose of two million cells per kilogram, and we look forward to additional data as we continue to advance this promising regenerative cell therapy through clinical development."

This Phase I study is designed as a multi-center, open-label, dose-escalating study to evaluate the safety of 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 is 12 months. The patients in the study will be 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 Data Safety Monitoring Board. 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.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel 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. 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 the timing and plans relating to its clinical trials, the safety of PLX-R18 in the clinical trial and the early signals of efficacy in improving blood counts observed in the clinical 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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