



Pluristem to Present First Cohort Data from PLX-R18 Hematological Study at American Society of Hematology's (ASH) Annual Meeting

- *Clinical data from the first cohort of Phase I study for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation.*
- *Program was granted an FDA Orphan Drug Designation*

HAIFA, ISRAEL, November 28, 2018 - [Pluristem Therapeutics Inc.](#) (NASDAQ: PSTI, TASE: PSTI), (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that the company will present data from the first cohort of its Phase I study of PLX-R18 cells for the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT) at the [American Society of Hematology's](#) (ASH) 60th Annual meeting to be held in San Diego, California, on December 1-4, 2018.

About the study

A Phase I study of PLX-R18 cells to treat incomplete hematopoietic recovery following HCT is ongoing in U.S. and Israel. The trial is designed as a multi-center, open-label, dose-escalating study to evaluate the safety of intramuscular injections (IM) of PLX-R18 cells in 24 subjects with incomplete hematopoietic recovery persisting for at least 4 months after HCT. The 24 patients in the study will be enrolled into three treatment groups: two administrations of 1 million PLX-R18 cells (n=3), two administrations of 2 million PLX-R18 cells (n=6), two administrations of 4 million PLX-R18 cells (n=15). The primary endpoint will be safety which will be assessed at the end of each cohort by an external safety committee. There will also be exploratory endpoints, 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. The 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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