Pluristem Therapeutics Announces FDA Orphan Drug Designation for PLX cell therapy for the Treatment of Graft Failure and Incomplete Recovery Following Hematopoietic Cell Transplantation

HAIFA, Israel, September 25, 2018 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to the Company's PLX cell therapy for the treatment of graft failure and incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT).

"We believe the FDA's decision to grant Orphan Drug Designation to PLX cell therapy for the treatment of graft failure and incomplete hematopoietic recovery reflects the potential of this regenerative therapy to improve outcomes in this underserved patient population," said Yaky Yanay, Co-CEO and President of Pluristem. "We look forward to data from our ongoing Phase 1 clinical trial as we work to efficiently advance this novel therapy through clinical development for this and other hematopoietic indications."

Pluristem's product PLX-R18 is currently being evaluated for the treatment of insufficient hematopoietic recovery following bone marrow transplantation in an ongoing Phase 1 clinical trial in the U.S. and Israel. The trial is designed to evaluate the safety of intramuscular (IM) injections of PLX-R18 cells in 24 subjects with incomplete hematopoietic recovery persisting for at least 4 months after HCT, with a 12-month follow-up period. The primary endpoint is safety. Exploratory endpoints include 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.

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for underserved patient populations, or rare disorders. Orphan drug designation provides to the Company certain benefits, including market exclusivity upon regulatory approval, if received, exemption of FDA application fees and tax credits for qualified clinical trials.

The FDA previously granted pluristem's regenerative medicine PLX cell product Orphan Drug Designation for the treatment of Pre-eclampsia, Aplastic Anemia, Berger disease and Acute Radiation Syndrome (ARS).

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, we are using forward-looking statements when we discuss our belief that the FDA's decision to grant Orphan Drug Designation to PLX-R18 for the treatment of graft failure and incomplete hematopoietic recovery reflects the potential of this regenerative therapy to improve outcomes in this underserved patient population. 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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