Pluristem Announces End of Patient Enrollment in its Phase I Hematology Study

Top line efficacy results expected Q1 2021

HAIFA, Israel, August 19, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today it has completed patient enrollment in its Phase I study evaluating PLX-R18 as a treatment for incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT), in the U.S. and in Israel.

Incomplete hematopoietic recovery poses a significant risk to HCT recipients who fail to respond to standard of care treatments, making them vulnerable to infections and bleeding. PLX-R18 may address the unmet need in this patient population by stimulating the regenerative potential of bone marrow where other treatments have proven ineffective. The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to PLX-R18 in this indication.

The Phase I multi-center, open-label, 3 cohort dose-escalating study is evaluating the safety of intramuscular (IM) injections of PLX-R18 cells in 20 subjects, with incomplete hematopoietic recovery persisting for at least 3 months after HCT. The follow up period is 12 months. Safety is the primary endpoint, with efficacy endpoints including changes in white blood cells, platelets counts, hemoglobin levels, changes in blood products requirements, and changes in quality of life. As previously reported, Pluristem expects to announce top line efficacy results during the first quarter of calendar year 2021.

“We are glad to meet an additional important clinical milestone that keeps us on track for our expected time to readout, and is one of four data readouts we expect to announce in the coming twelve months. We look forward to seeing data that may position PLX-R18 as an important drug candidate for hematological disorders. We would like to thank the medical teams across the clinical sites supporting our program in the most professional and caring way,” stated Pluristem CEO and President, Yaky Yanay.

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 trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials 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 expected timing of the top line results for its Phase I study and other readouts and the ability of PLX-R18 to address unmet needs in patients by stimulating the regenerative potential of the bone marrow. 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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