Pluristem reports positive topline Phase I results in innovative hematology program, which is first to study PLX-R18 in humans

- New therapy has potential to generate improved blood counts in all three blood cell lineages, a meaningful advantage over existing treatments
- The company will conduct an analyst and investor call on May 3, 2021, at 10am EDT

HAIFA, Israel, April 29, 2021 – Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE: PSTI), a leading regenerative medicine company, today reported positive topline results in its first study to evaluate the safety and exploratory efficacy of PLX-R18 in humans. The company's Phase I, open-label, dose-escalation study is evaluating the safety and exploratory efficacy of intramuscular injections of PLX-R18 in subjects with incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT).

Pluristem CEO and President, Yaky Yanay, said, "The promising topline results demonstrate insight into how PLX cells may provide a more effective therapeutic benefit than current technologies. We believe that PLX-R18 affects the regeneration activity of the hematopoietic cells. By supporting blood cell lineage's recovery, this approach could be used to address a variety of hematological deficiencies. We intend to push forward the clinical development of PLX-R18 with the goal of establishing it as the new standard of care in the field."

Poor graft function is a life-threatening complication for patients undergoing HCT. Current standard-of-care treatments do not develop satisfactory blood counts in some or all blood cell lineages. Consequently, patients are vulnerable to bleeding and recurrent infections, and require repeated costly transfusions of blood products, which only provide a short-term effect. Pluristem's PLX-R18 aims to improve the standard of care by stimulating the regenerative potential of the bone marrow. This potentially enhances the production of all three blood cell lineages, differentiating it from other products which target only one of the three blood cell lineages.

The study enrolled 21 patients in the U.S. and Israel, who were at least three months after the HCT procedure (median: 236 days), and had low blood counts in at least one blood cell lineage. They were assigned to one of three treatment arms: 1 million cells/kg, 2 million cells/kg or 4 million cells/kg. Each patient received two treatments of the assigned dose.

The results demonstrate that PLX-R18 has the potential to stimulate the implanted hematopoietic cells to realize their therapeutic potential and generate improved

blood counts over the long term in all three blood cell lineages at once – a meaningful advantage over other existing and proposed treatments.

Available data[1] at six-month follow-up demonstrates:

- PLX-R18 was well-tolerated with a favorable safety profile.
- Statistically significant improvement from baseline counts was observed in all cohorts for hemoglobin and platelet counts ($p<0.05$). The patients in the high dose arm (4 million cells/kg) exhibited statistically significant improvements in all three blood cells lineages ($p<0.01$).
- Approximately 60% of patients exhibited improvements in all three blood cell lineages: hemoglobin, neutrophil and platelet counts, that are above the initial criteria for inclusion in the study.
- 13 patients were transfusion dependent at baseline. Six of those became transfusion independent at six-month follow up. No patients who were transfusion independent at baseline became transfusion dependent.

The study supports previous preclinical results, conducted via the U.S. Food and Drug Administration's (FDA) Animal Rule in collaboration with the U.S. National Institutes of Health (NIH), in which PLX-R18 was found effective in treating bone marrow failure from Acute Radiation Syndrome (ARS).

PLX-R18 is the first product candidate manufactured using Pluristem's proprietary serum-free media on its 3D bioreactor system.

The company will conduct an analyst and investor call on May 3, 2021, at 10am EDT, for registration: https://Veidan.activetrail.biz/pluristem

[1] Data from the six-month follow-up is available for 14 of the 21 treated patients: one patient was terminated early, three patients missed the 6-month visit and three died prior to the 6-month visit (two fatal events in the 2 million cell dose, and one fatal event in the 4 million cell dose). All fatal events in the study were considered unrelated to the study treatment. Mortality rates were in line with publicly available information (references: Gao et al 2020, , Halahleh et al 2021, Tang et al 2018, Sun et al. 2015, Zhao et al 2019)

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, 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 that PLX cells may provide a more effective therapeutic benefit than current technologies, that PLX-R18 may potentially enhance the production of three blood cell lineages, the belief that PLX-R18 affects the regeneration activity of the hematopoietic cells and its intention to push forward with the clinical development of PLX-R18 with the goal of establishing it as the new standard of care in the field. 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.

Contact:

Dana Rubin
Director of Investor Relations
972-74-7107194
danar@pluristem.com