Pluristem Releases PLX-R18 Hematology Phase I Study Results: Data Show Increase in All Blood Lines and Reduction in Blood Transfusions

- Results show the potential in the use of PLX-R18 for meaningful advantage over other existing and proposed treatments in post hematopoietic cell transplantation (HCT) patients.
- PLX-R18 reduced mortality from 29% to 18%[1] and was well-tolerated with a favorable safety profile.
- PLX-R18 was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of graft failure and incomplete hematopoietic recovery following HCT and the prevention and treatment of acute radiation syndrome (ARS).
- In 2018, the FDA cleared Pluristem's Investigational New Drug (IND) application for PLX-R18 in the treatment of ARS.

HAIFA, Israel, March 23, 2022 – Pluristem Therapeutics Inc. (Nasdaq: PSTI) (TASE: PSTI), a leading biotechnology company developing novel cell therapies, today announced positive final results from its innovative hematology Phase I study to evaluate the safety and exploratory efficacy of intramuscular injections of PLX-R18 in subjects with incomplete hematopoietic recovery following HCT.

Incomplete hematopoietic recovery, or poor graft function (PGF), is a life-threatening complication for patients undergoing HCT. Current standard-of-care treatments do not result in 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 short-term benefits.

Data collated 12 months post-treatment with PLX-R18 demonstrate that:

1. PLX-R18 was well-tolerated with a favorable safety profile.
2. Patients treated with PLX-R18 showed an increase in all three blood cell types compared to baseline with platelets ($p<0.001$), hemoglobin ($p=0.01$) and neutrophils ($p=0.15$) levels increasing as early as 1 month following PLX-R18 administration and enduring up to 12 months following treatment.

[1] When compared to data obtained from the CIBMTR registry during a 12-month interval from first observation. First observation was defined as the day of first PLX-R18 treatment for the Phase I patients and as day 100 post-HCT for the CIBMTR population. See About the CIBMTR for more details.

3. Following PLX-R18 treatment, the number of transfused units decreased from a mean monthly number of 5.09 for platelets and 2.91 for red blood cells at baseline to 0.55 for platelets (p=0.045) and 0 for red blood cells (p=0.0005) at 12 months.
4. The observed annual mortality rate following PLX-R18 administration was 18% compared to 29% in a cohort of allogeneic HCT recipients with incomplete hematopoietic recovery, obtained from the Center for International Blood and Marrow Transplant Research (CIBMTR) registry, representing a similar patient population.[1]

PLX-R18 cell therapy was previously granted an orphan drug designation by the FDA for the treatment of graft failure and incomplete hematopoietic recovery following HCT and for ARS. The final results of the Phase I study reinforce the preclinical results of studies conducted under the FDA's Animal Rule, in collaboration with the U.S. National Institutes of Health (NIH) and the U.S. Department of Defense (DOD), in which PLX-R18 was found to be effective in supporting the recovery of bone marrow failure resulting from ARS. In addition, the FDA previously cleared Pluristem's IND application for PLX-R18 in the treatment of ARS. The IND allows Pluristem to treat victims who may have been acutely exposed to high dose radiation due to a nuclear attack or accident.

"PLX-R18 aims to improve the standard of care by stimulating the regenerative potential of the bone marrow, and we are gratified by results that I believe show we are on track to do so," said Pluristem Chief Executive Officer and President Yaky Yanay. "A quick and effective way to improve the hematological profile of sick patients—resulting in faster recovery and decreased transfusions—would be a game-changer for the field, and we will continue to explore its clinical applications. The FDA's recognition of PLX-R18's potential to treat ARS is also significant. This treatment potentially carries great significance for current events in Ukraine and Europe, providing hope for treatment in the case of a nuclear event. We are proud of this product line, which might hold the key to promoting wellbeing, improving the standard of care, and possibly saving lives."

About Pluristem

Pluristem is pushing the boundaries of science and engineering to produce cell-based products for various industries on a global scale. The Company's cell manufacturing platform is a patented and validated 3D cell expansion system, which is uniquely precise, cost-effective, and consistent from batch to batch. Pluristem currently operates

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in the regenerative medicine and food tech sectors and aims to establish partnerships that leverage the Company's cell-based technology platform for additional applications. Pluristem's placental cell-based therapies advance the field of regenerative medicine, with potentially groundbreaking applications for treating damaged muscle, hematology deficiencies, and inflammation. The Company also recently launched a landmark collaboration with Israeli food giant Tnuva to produce cultured food products with sustainability as a guiding principle.

About the Study and PLX-R18

This Phase I study was designed as a multi-center, open-label, dose-escalating study to evaluate the safety of intramuscular (IM) injections of PLX-R18 cells in 21 patients with incomplete hematopoietic recovery/PGF persisting for at least three months after HCT. The follow-up period for safety was 12 months. Patients in the study were enrolled into one of three chronological treatment groups receiving two administrations, 1 week apart, of PLX-R18 at a dose of 1 million PLX-R18 cells/kg (n=3), 2 million PLX-R18 cells/kg (n=6), or 4 million PLX-R18 cells/kg (n=12). The primary endpoint was safety, and it was assessed throughout the study, and specifically at the end of each cohort, by an external DSMB. In addition, exploratory efficacy variables were collected, including changes in blood counts, transfusion frequency, and a shift from transfusion dependence to transfusion independence.

The PLX-R18 cell therapy product secretes a combination of cytokines, including IL-6, IL-8, SCF, G-CSF, MCP1, and Gro-β, and is designed to stimulate the regeneration of damaged bone marrow to produce blood cells lineages (white, red, and platelets). As efficacy studies are not permitted in humans for the ARS indication, pre-clinical studies were conducted via the FDA animal rule pathway to evaluate Pluristem's PLX-R18 as a medical countermeasure for that indication. These studies were conducted and funded by the U.S. government (NIH, DOD).

About the CIBMTR

The Center for International Blood and Marrow Transplant Research is a nonprofit research collaboration between the National Marrow Donor Program (NMDP)/Be The Match, in Minneapolis, and the Medical College of Wisconsin, in Milwaukee. The CIBMTR collaborates with the global scientific community to increase survival and enrich the quality of life for patients. The CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of centers, and a unique database of long-term clinical data for more than 600,000 people who have received HCT and other cellular therapies. Learn more at cibmtr.org or follow the CIBMTR on Facebook, LinkedIn, or on Twitter.

From the CIBMTR registry, Pluristem selected patients aged ≥18 years at time of first allogeneic HCT for a hematologic malignancy in the United States between January 2017 and June 2020 with characteristics as similar as possible to the patients treated with PLX-R18 in the Phase I study. Such values include full donor chimerism at ≤30 days post-HCT, disease in remission at 100 days post-HCT, and no active Grade III/IV acute GVHD or severe chronic GVHD or CMV infection ≤30 days post-HCT. These patients were classified as PGF based on platelet count $<50 \times 10^9$ cells/L by day 100 post-HCT. Mortality rates for this group were then compared to a comparable subset of the Phase I (n=17) study who had platelet count $<50 \times 10^9$ cells/L at study baseline and were <300 days post-HCT.

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 potential safety, efficacy and benefits of PLX-R18 and that it aims to provide the standard of care and is on track to do so and the potential significance of PLX-R18 in case of a nuclear event. These forward-looking statements and their implications are based on the current expectations of Pluristem's management 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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