Following Approval of Israel’s Ministry of Health, Pluristem Extends its Trial of PLX-R18 to Treat Insufficient Hematopoietic Recovery after Bone Marrow Transplant and Opens Clinical Centers in Israel

- Israeli clinical sites will join an ongoing U.S. Phase I trial
- Hadassah Medical Center and Rambam Hospital have cleared the trial and recruitment is set to begin

HAIFA, ISRAEL, October 26, 2017 -- Pluristem Therapeutics Inc. (Nasdaq: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that it received approval from Israel’s Ministry of Health to initiate a Phase I trial studying the company’s PLX-R18 cell therapy as a treatment for insufficient hematopoietic recovery following hematopoietic cell transplantation (HCT). As previously announced, the trial was also approved by the U.S. Food and Drug Administration (FDA) and recruitment is ongoing in the United States. Up to 30 patients will be recruited in total from the United States and Israeli trial sites. Ethics committees at both Hadassah Medical Center and Rambam Hospital in Israel have cleared the trial and recruitment can begin in both hospitals.

“We’re very pleased with the Israeli Ministry of Health’s vote of confidence in our innovative therapies and efforts to provide treatments for a range of hematopoietic conditions, including insufficient recovery from hematopoietic stem cell transplants,” stated Zami Aberman, Pluristem’s Co-CEO and Chairman. “Hadassah Medical Center and Rambam Hospital are well known for their groundbreaking treatments and we are happy for this collaboration. Previous studies with PLX-R18 cells have yielded promising results, which we believe suggest that our cells can improve patient outcomes.”

Pluristem’s PLX-R18 cells are in late-stage development as a treatment for acute radiation syndrome (ARS) and the program is supported by the U.S. National Institutes of Health (NIH), which is conducting the trials. The cells are also being studied by the U.S. Department of Defense and the Fukushima Medical University in Japan. Pluristem recently reported a new granted patent to cover PLX-R18 cells in additional indications related to the bone marrow’s inability to produce blood cells, including autoimmune diseases, genetic disorders, chemotherapy, and radiation therapy.

Bone Marrow Failure and HCT

Bone marrow failure is the inability of bone marrow to produce sufficient numbers of platelets, white or red blood cells. This inability may result in serious illness or death, because these cells are necessary to prevent hemorrhage, infection or severe anemia. Bone marrow failure can be caused either by medical conditions such as aplastic anemia, myelodysplastic syndrome, hematologic malignancies, or as a side effect of radiation or chemotherapy cancer treatment. The incidence of bone marrow failure resulting from these conditions varies widely, but is increasing.
The only known cure for bone marrow failure is HCT, although supportive therapies and treatments can reduce symptoms and prolong life for some patients. The hematopoietic cells for HCT can come from a donor or from the patient, and can be harvested from peripheral blood, bone marrow or umbilical cord blood. Transplant patients require extensive care and monitoring, and sometimes need intensive treatment for complications. In cases of incomplete engraftment, blood cell counts are insufficient, causing the patient to be at high risk of severe or lethal complications. In severe cases, the patient may need to undergo the arduous and dangerous process of a second transplant.

About PLX-R18

PLX-R18 is Pluristem’s second cell therapy product in development. It is designed to treat bone marrow that is unable to produce enough blood cells due to a variety of causes including ARS, certain cancers or cancer treatments, or immune-mediated bone marrow failure. PLX-R18’s first animal studies in ARS were performed in collaboration with Prof. Gorodetsky at Hadassah Medical Center. Further preclinical data from trials conducted by the NIH, Hadassah, the Charite in Berlin and other prominent research institutions have shown that PLX-R18 cells secrete a range of specific proteins that trigger the regeneration of bone marrow hematopoietic cells, thereby supporting the recovery of blood cell production. Pluristem is currently enrolling patients in a U.S. Phase I trial of PLX-R18 in incomplete bone marrow recovery following HCT and is preparing for a pivotal trial in ARS.

About Pluristem Therapeutics

Pluristem Therapeutics is a leading developer of placenta-derived cell therapy products with patented PLX (PLacental eXpanded) cells entering late-stage trials in several indications. Our PLX cell products each release a different 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 3D expansion technology and can be administered to patients without tissue matching or immunosuppression. Pluristem has Company-owned and operated, GMP-certified manufacturing and research facilities, a strong intellectual property position, and strategic relationships with major research and U.S. government institutions.

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 timing and patient recruitment of its proposed Phase I trial studying the company’s PLX-R18 cell therapy and its belief that its cells can improve patient outcomes. 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:

Karine Kleinhaus, MD, MPH
Divisional VP, North America
1-914-512-4109
karinek@pluristem.com

Efrat Kaduri
Investor and Public Relations Manager
972-74-7108600
efratk@pluristem.com