



Pluristem Reports First Quarter Fiscal 2018 Corporate and Financial Highlights

HAIFA, Israel, November 14, 2017- [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, today reported financial results and corporate developments for its first quarter of fiscal 2018 ended September 30, 2017.

“Our activities in this quarter demonstrate our continued drive to develop and commercialize cell therapy products that have the potential to help millions of patients facing unmet medical needs, while also generating value for our shareholders,” stated Pluristem Chairman and Co-CEO, Zami Aberman. “We have seen a burgeoning interest in our cell therapy products from external parties including key regulatory agencies, government bodies, business partners, physicians and patients around the world. We believe this interest shows broad confidence that Pluristem can fill a significant gap in the current global healthcare system. As we come closer to marketing approval and commercialization, we believe Pluristem maintains a significant advantage in the industry with our proprietary 3D manufacturing technology, strong intellectual property and business partnerships, and positive data from our completed studies.”

Clinical and Corporate Highlights:

PLX-PAD Leading Programs Receive a Vote of Confidence from Key Regulatory Agencies with Fast Track Designation Granted for Phase III CLI Study by the U.S. FDA and Positive Feedback from the FDA and EMA for Phase III Hip Fracture Trial

Pluristem’s multinational Phase III study of PLX-PAD cells in the treatment of Critical Limb Ischemia (CLI) was granted Fast Track Designation from the U.S. Food and Drug Administration (FDA) and is currently enrolling patients in the U.S. and Europe. Fast Track Designation increases the chance of a priority review by the FDA. This trial was recently awarded an \$8 million grant from the European Horizon 2020 program.

The Company reported that in previous discussions with the FDA and the European Medicines Agency (EMA), it received positive feedback on the proposed study design and endpoints for its Phase III trial in the treatment of muscle recovery following arthroplasty for hip fracture. Pluristem plans to submit the Investigational New Drug (IND) and Clinical Trial Application (CTA) for the trial in the coming months. This trial was recently awarded an \$8.7 million grant from the European Horizon 2020 program.

PLX-R18 Receives Orphan Drug Designation for the Treatment of ARS; Pluristem Extends its Trial in the Treatment of Insufficient Hematopoietic Recovery Following Bone Marrow Transplant and Opens Clinical Centers in Israel

Pluristem’s PLX-R18 was granted Orphan Drug Designation by the FDA as a treatment for Acute Radiation Syndrome (ARS), which may accelerate the path to potential marketing approval and includes a seven year grant market exclusivity upon marketing approval. Pluristem’s ARS trial is supported and conducted by the National Institutes of Health (NIH), the U.S. Department of Defense and Fukushima Medical University.

Pluristem reported that, following approval from Israel's Ministry of Health, it will open clinical centers in Israel for its Phase I trial of PLX-R18 cell therapy as a treatment for insufficient hematopoietic recovery following hematopoietic cell transplantation (HCT). The trial is already recruiting patients in the United States. Up to 30 patients will be recruited in total from the United States and Israel.

Pluristem Expands its Pipeline and Enters into Agreement for Investigator Initiated Study in Chronic GvHD

Pluristem signed an agreement with Tel Aviv Sourasky Medical Center (Ichilov Hospital) to conduct a Phase I/II trial in PLX-PAD cell therapy for the treatment of Steroid-Refractory Chronic Graft-versus-Host-Disease (GvHD).

Pluristem Was Issued Three Patents in Support of its PLX Products

Pluristem was granted three significant patents. Two of the patents were issued by the Hong Kong Patents Registry for cell therapy products related to CLI and muscle regeneration. The third patent was granted to Pluristem by the European Patent Office for PLX-R18 to be used to treat a host of new indications, including ARS, genetic disorders, and autoimmune diseases, while also supporting chemotherapy treatments.

Financial Update:

As of September 30, 2017, Pluristem had \$21.3 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. The Company's net cash used for operating activities for the quarter ended September 30, 2017 was \$5.2 million. In addition, during October, the company conducted a public offering in Israel for aggregate gross proceeds of \$15.1million.

Pluristem also announced that a \$7.9 million non-dilutive grant from the European Horizon 2020 program has been awarded to nTRACK, a collaborative project designed to study nanoparticle effects on PLX-PAD cell viability and functionality.

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 its belief that broad interest in its products by key regulatory agencies, government bodies, business partners, physicians and patients around the world reflects confidence that it can fill a significant gap in the current global healthcare system, its belief that it holds a significant advantage in the industry, that the fast track designation of its multinational Phase III study of PLX-PAD cells in the treatment of CLI increases the chance of a priority review by the FDA, its plans to submit an IND and CTA for the Phase III trial in the treatment of muscle recovery following

arthroplasty for hip fracture, the potential accelerated path to potential marketing approval of its PLX-R18 due to its being granted Orphan Drug Designation by the FDA, its plan to open clinical trial centers in Israel and the recruitment of patients for its Phase I trial of PLX-R18 cell therapy as a treatment for insufficient hematopoietic recovery following HCT and the timing of its various planned trials and studies. 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
Head of Investor and Public Relations
972-74-7108600
efratk@pluristem.com