



Pluristem Reports First Quarter Fiscal 2017 Corporate and Financial Highlights

- *\$30 million equity investment term sheet signed with large Chinese investment fund active in the healthcare industry*
- *Significant advancement towards initiation of pivotal Phase III trials*
 - *U.S. FDA provided positive feedback and UK's MHRA approved initiation of the multinational pivotal Phase III CLI trial*
 - *Received scientific advice from EMA, and preparing a pre-IND meeting with FDA on Phase III trial in recovery following surgery for hip fracture*
 - *Advancing towards pivotal trial for ARS with ongoing dose-selection trial supported and conducted by the U.S. NIH's NIAID*
- *Appointed Principal Investigator & selected sites for FDA-cleared Phase I HCT trial in U.S.*

HAIFA, ISRAEL, November 15, 2016 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, reported financial results and provided corporate and clinical developments for the first quarter of fiscal year 2017, ended September 30, 2016.

“During the first quarter we executed important additional steps to initiate our pivotal clinical trials, and expect to begin enrolling for our Phase III trial in critical limb ischemia during the first half of 2017. We have consulted with the European Medicines Agency (EMA) and are preparing for a pre-IND meeting with the U.S. Food and Drug Administration (FDA) on a pivotal Phase III trial in recovery after surgery for hip fracture, anticipate completing patient enrollment in a multinational Phase II trial, and have clearance to start a Phase I trial with our second product, which has opportunities for interim data,” stated Pluristem’s Chairman and CEO Zami Aberman. “We are very optimistic about our ability to conduct and fund pivotal Phase III studies that, given positive results, are expected to bring our PLX cells to commercialization in significant markets.”

Clinical and Corporate Highlights Include:

- *U.S. FDA provided positive feedback on multinational pivotal Phase III CLI Trial & the UK's MHRA approved initiation of the study in the UK*

The U.S. Food and Drug Administration gave Pluristem positive feedback regarding its pivotal Phase III CLI trial. The Phase III trial is intended to support a biologics license application (BLA) in the U.S. Shortly following the end of the first quarter, the United Kingdom’s Medicines & Healthcare Products Regulatory Agency (MHRA) cleared Pluristem to begin enrolling in the UK for that trial. The trial will take place in the U.S. and Europe, where Pluristem’s CLI program was

previously selected by the EMA for its Adaptive Pathways pilot project, which may allow for conditional marketing approval after a single pivotal study. In September, Pluristem conducted a symposium on peripheral artery disease at the Third National Conference of the German, Austrian and Swiss Societies of Vascular Medicine in Dresden, Germany. During the conference, a meeting was organized with leading vascular specialists to identify potential investigators for the CLI study.

- ***Preparing for Phase III trial in recovery after surgery for hip fracture***

Pluristem has been preparing for a Phase III trial of PLX-PAD to evaluate its efficacy to improve recovery following surgery for femoral neck fracture, which is the most common type of hip fracture in the elderly population. Pluristem previously received scientific advice from the EMA on the study protocol as a single pivotal trial in this indication through the Adaptive Pathways Project, and plans to meet with the FDA in early 2017.

- ***Global Phase II Intermittent Claudication trial nearing completion***

The Company expects to complete enrollment of all 170 patients by the end of 2016 and to report trial results in late 2017. To date 167 patients have been enrolled.

- ***Appointed Principal Investigator and completed sites selection for Phase I trial in hematologic indication***

Dr. Hillard Lazarus of Case Western Reserve University was appointed as the Principal Investigator of Pluristem's Phase I trial of PLX-R18 cells in the treatment of incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT). The FDA previously cleared the Phase I trial to begin enrollment, and a leading contract research organization selected the sites for the trial.

- ***Ongoing dose-optimization trial in acute radiation syndrome (ARS)***

Pluristem is anticipating data from an ongoing dose-selection trial in acute radiation syndrome (ARS) being conducted and supported by the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases. Upon determining the optimal dose, a pivotal trial in large animals is planned and the results, if positive, will be used to support a Biologics License Application (BLA) submission of PLX-R18 for this indication under the Animal Rule regulatory pathway.

- ***\$30 Million equity investment binding term sheet***

Following the end of the first fiscal quarter, Pluristem signed a binding term sheet for an investment of approximately \$30,000,000 by China-based Innovative Medical Management Co., Ltd., a healthcare-focused investment fund. Pursuant to the term sheet, approximately 16,890,000 shares of Pluristem common stock will be sold at \$1.77 per share, in addition to warrants. Pluristem and Innovative Medical plan to enter into a definitive agreement no later than December 26, 2016.

Financial Update:

As of September 30, 2016, Pluristem had approximately \$29.3 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. The Company's net cash used for operating activities was \$3.9 million during the first quarter. Pluristem anticipates being

well capitalized to conduct the clinical trials planned for initiation in the coming quarters, as well as ongoing R&D efforts to support development of future products.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cell products release a range of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring no tissue matching prior to administration.

Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, we are using forward-looking statements when we discuss our financial position, closing of \$30 million investment, timing and terms of such investment and sufficiency of capital resources, our plans with respect to our existing and future preclinical and clinical trials, including initiation, enrollment, successful completion reporting of results and timing of all of the above, discussions with regulatory agencies and receipt of favorable outcomes from such discussions. 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; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; 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; our patents may not be sufficient; our products may harm recipients; changes in legislation; 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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