



Pluristem Reports Second Quarter Fiscal 2016 Financial Highlights and Clinical Development Update

*Strong Balance Sheet, Two Active Clinical Development Programs in the U.S.
Accelerated Pathways to Commercialization in Japan & Europe*

HAIFA, ISRAEL, February 10, 2016 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today reported financial highlights for its second quarter ended December 31, 2015, and provided a clinical and corporate updates.

“We achieved significant clinical milestones during our second fiscal quarter. PLX-R18, our second product, was cleared by the FDA for clinical studies. The PLX-R18 product is designed to be an entirely new and innovative treatment approach for a wide variety of hematopoietic disorders, and might save the lives of severely ill patients with no alternative treatment options. Receipt of an Orphan Drug Designation from the FDA for PLX-PAD cells in the treatment of severe preeclampsia encourages us to move forward with the development plan of this indication,” stated Pluristem Chairman and CEO Zami Aberman. “In both Europe and Japan, we are working with regulators to expedite commercialization of PLX-PAD in the treatment of critical limb ischemia, and we are very pleased that Japanese regulators approved the protocol for our pivotal Phase 2 trial in that indication.”

Financial Update:

As of December 31, 2015, Pluristem had \$44 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. The Company’s net cash used for operating activities was \$ 3.6 million for the second quarter. As a result, Pluristem anticipates being well capitalized to conduct the clinical trials that are planned for initiation in 2016, as well as ongoing R&D efforts to support future products approval.

Clinical and Corporate Highlights for Q2 Fiscal 2016 Include:

Two Clinical Development Programs in the U.S.

- The U.S. Food and Drug Administration (FDA) granted Pluristem clearance to initiate a clinical trial of PLX-R18 in the treatment of insufficient hematopoietic recovery following hematopoietic cell transplantation (e.g., bone marrow or umbilical cord blood transplants). A Phase I trial is expected to begin in 2016, and will allow for the possibility of interim

data analysis. Pluristem intends to pursue early market access for PLX-R18 in the U.S. via a Breakthrough Therapy Designation.

- At the American Society of Hematology's (ASH) 57th Annual Meeting, Pluristem presented new data on PLX-R18 in a poster presentation titled "Mechanism of Action of PLX-R18, a Placental-Derived Cellular Therapy for the Treatment of Radiation-Induced Bone Marrow Failure."
- The FDA has granted PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia.
- In December, a peer-reviewed article was published in Clinical Science which describes the mechanism of action of PLX-PAD in the treatment of preeclampsia and indicates placental cells' superiority over cells derived from other sources. This marked the first published study comparing the therapeutic outcome of placenta-derived cells to cells derived from bone marrow or fat tissue.

Expedited Path to Commercialization in Japan and Europe

- Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and Pluristem reached an agreement on the design of the final trial for conditional approval of PLX-PAD cells in the treatment of critical limb ischemia (CLI). In the 75-patient trial, efficacy and safety outcomes will be measured at nine months after administration of the first dose.
- Pluristem's PLX-PAD cells were previously selected by the European Medicines Agency (EMA) for its Adaptive Pathways project in the indication of CLI. During its second fiscal quarter, Pluristem continued to benefit from the Adaptive Pathways committee's guidance as it develops its clinical program targeting the Conditional Marketing Authorization accelerated regulatory pathway in Europe.

Corporate Collaborations

- In December, Pluristem and United Therapeutics ended their licensing agreement for the development of PLX-PAD for the treatment of pulmonary arterial hypertension (PAH). Pluristem regained full rights to PLX-PAD in this indication, as well as all clinical data and regulatory submissions, allowing the Company to move forward with the clinical development program and seek other licensing partners. Encouraging data was reported for the first cohort in this Phase 1 trial.
- Pluristem and the Berlin-Brandenburg Center for Regenerative Therapy at Charité - University Medicine Berlin expanded their five-year collaborative research agreement to include orthopedic indications. The parties intend to jointly advance the development of PLX-PAD cells in certain orthopedic indications that could be eligible for Europe's Adaptive Pathways Project.
- Pluristem signed a Memorandum of Understanding (MOU) for a collaboration with Fukushima Medical University, Fukushima Global Medical Science Center. The purpose of the collaboration is to develop Pluristem's PLX-R18 cells for the treatment of ARS, and for morbidities following radiotherapy in cancer patients.

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 cells release a cocktail 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 the potential of PLX-R18 to be an entirely new and innovative treatment approach for a wide variety of hematopoietic disorders, and to save the lives of severely ill patients with no alternative treatment options, and moving forward with development plan of this indication, when we discuss expediting commercialization of PLX-PAD in the treatment of critical limb ischemia, when we discuss our anticipation to be well capitalized to conduct the clinical trials that are planned for initiation in 2016, as well as ongoing R&D efforts to support future products approval, when we discuss our clinical trials and studies, including timing for initiation, when we discuss pursuing early market access for PLX-R18 in the U.S. via a Breakthrough Therapy Designation, and when we discuss our collaborations with the Berlin-Brandenburg Center for Regenerative Therapy at Charité - University Medicine Berlin and with Fukushima Medical University. 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. 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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