



## **Pluristem Reports Second Quarter Fiscal 2017 Highlights & Provides Calendar 2017 Outlook**

HAIFA, Israel, February 13, 2017 -- Pluristem Therapeutics Inc. (Nasdaq: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today reported financial update and corporate and clinical developments for the second quarter of fiscal 2017, ended December 31, 2016.

"Driven by our commitment to help patients with serious, unmet medical needs, we are continuously working towards our goals for 2017 which will advance our cell therapy products towards commercialization, bring significant value to our shareholders and make an important difference in millions of patients' lives," stated Pluristem Chairman and CEO Zami Aberman.

"While we move multiple indications into advanced stage clinical studies, we continue to maintain a significant advantage in the field with our commercial-grade cell production capacity, ground-breaking manufacturing technology, and proprietary GMP manufacturing facility that we own and operate.

"Regenerative medicine in general, and PLX cell therapy in particular will have tremendous benefits on healthcare economics based on efficacy, the treatments' non-invasive nature, and our production capacity enabling us to supply allogeneic cells to a broad population."

"Pluristem is well positioned to progress towards commercialization, and with a strong balance sheet for upcoming negotiations with potential commercial partners," Aberman concluded.

### **Clinical and Corporate Highlights and Upcoming Milestones Include:**

- **Pivotal Phase III CLI Trial Cleared to Commence Enrollment in U.S. and EU in H1 2017**

Pluristem achieved significant strides towards marketing approval of PLX-PAD in the treatment of critical limb ischemia (CLI). Study initiation of the pivotal Phase III trial in CLI received clearance from regulatory authorities in the United States, United Kingdom and Germany. Based on these clearances, the Company expects to begin enrolling patients in this study in the first half of 2017.

An interim analysis of data collected on the first half of recruited patients is planned, potentially leading to early conditional marketing approval in Europe via the EMA adaptive pathway pilot project. Full enrollment is to be completed as planned to pursue full marketing approval in the U.S and Europe.

- **Data from Phase II PLX-PAD Trial in IC:**

In January 2017 Pluristem completed enrollment of all 172 patients in a multinational Phase II trial of PLX-PAD in the treatment of intermittent claudication (IC), an early stage of peripheral artery disease (PAD). Data from this study, expected in the first half of 2018, may also support the planned Biologics License Application (BLA) for PLX-PAD in the treatment of CLI in the U.S.

- **Joint Venture and \$11 million investment from Sosei and Partners Advances Pluristem into Pivotal Trial in Japanese Market**

Pluristem signed a term sheet with Sosei Corporate Venture Capital LTD., a Japanese pharmaceutical company, to form a joint venture for the development and commercialization of PLX-PAD for the treatment of CLI in Japan. Pursuant to the executed term sheet, Sosei and its partners will invest \$11 million into the joint venture to support a pivotal trial of PLX-PAD in CLI in Japan. This 75-patient trial was previously cleared by the Japanese regulatory authority. Results could potentially serve as the basis for conditional marketing approval under the PMDA accelerated pathway, for which Pluristem has already been accepted. Finalization of the definitive agreement with Sosei is anticipated by March 31, 2017.

- **NIH Advances its Studies of PLX-R18 for Treatment of ARS**

The U.S. National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) is completing the dose-selection trials for PLX-R18 in the treatment of acute radiation syndrome (ARS). The results of these studies, conducted and funded by the NIAID, are intended to serve as the basis for a final pivotal trial in large animals, which will provide the evidence of efficacy for approval under the FDA's Animal Rule. Pluristem is pursuing a government contract to stockpile the product for use in the case of a nuclear catastrophe.

- **Enrollment in Phase I Hematologic Indication of PLX-R18**

In the first quarter of 2017, Pluristem expects to initiate patient enrollment in its FDA-cleared, open-label Phase I trial of PLX-R18 to treat incomplete engraftment of hematopoietic cell transplant. Data will be available on an ongoing basis as this is an open label study.

- **FDA and EMA Submission for Phase III Clinical Trial of PLX-PAD in Recovery Following Hip Fracture**

Pluristem plans to obtain clearance of its protocol for a Phase III trial of PLX-PAD cells in recovery after surgery for hip fracture, from both U.S. and European regulators, during the second half of 2017.

- **\$900,000 Grant to Fund Studies at New York Blood Center for PLX-R18 in UCB Transplantation**

Pluristem will collaborate with the New York Blood Center (NYBC) on preclinical studies of PLX-R18 cells to enhance the efficacy of umbilical cord blood (UCB) transplantation. The project has been selected to receive \$900,000 from the Israel-U.S. Binational Industrial Research and Development Foundation (BIRD).

#### **Financial Update:**

As of December 31, 2016, Pluristem had \$21.9 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. The Company's net cash used for operating activities was \$5.8 million for this quarter. In January 2017, the Company completed a public offering of common stock and warrants with gross proceeds of \$17.25 million. Pluristem also signed a binding term sheet for a \$30M investment from Innovative Medical, a subsidiary of ZSVC. Finalization of the term sheet was delayed due

to a new Chinese monetary policy. The parties continue the discussions with respect to the definitive agreement until they have received further clarification about such policies, which is expected during the first half of 2017.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products entering pivotal trials in 2017. Pluristem 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 partnerships; 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, the timing of execution of definitive agreements with Innovative Medical and the closing of their \$30 million investment, the timing of the execution of definitive agreements with Sosei, the 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. Further, although Pluristem has signed binding term sheets with each of Innovative Medical and Sosei, respectively, it may not be successful in negotiating definitive documentation with either party by the date expected or at all, and even if successful, the transactions may not be completed if the conditions to closing are not met. 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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