



## **Pluristem Provides Fiscal Year 2016 Corporate and Financial Highlights**

- Executing an efficient commercialization strategy with three planned late stage pivotal trials
- Innovative regulatory pathway clearances including EU adaptive pathway and Japanese accelerated pathway for regenerative medicine, allowing early marketing access
- FDA clearance granted for clinical trial of second product, PLX-R18, in a hematological indication
- NIH launches advance studies for acute radiation syndrome
- Significant support by federal and governmental agencies for clinical development of PLX products

**HAIFA, ISRAEL, September 12, 2016** -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, reported financial results and summarized corporate and clinical developments for its fiscal year ended June 30, 2016.

“Over the past twelve months, Pluristem has made major progress in executing its long-term strategy to target accelerated regulatory pathways and shortening the time to market for its products. These achievements position us to launch a series of multinational pivotal phase III trials, targeting major markets with significant unmet needs,” stated Pluristem Chairman and CEO Zami Aberman.

“The potential of PLX cells has been acknowledged by regulators and innovation programs from around the globe. Our clinical development programs have been selected for accelerated regulatory pathways to market, and we have been awarded massive grants that enable us to move quickly and efficiently towards pivotal studies.”

“We are now entering an exciting and very meaningful stage for the company and are extremely confident in Pluristem’s ability to execute on multiple fronts to bring the most innovative and effective cell therapies to market,” concluded Aberman.

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

- Multinational Phase III CLI Trials to Commence

In the coming quarters, Pluristem plans to commence enrolling an estimated 250 patients through clinical sites in the U.S. and Europe for its Phase III trial of PLX-PAD cells in the treatment of CLI, a \$12 billion global market. The Company intends to utilize this study as a single pivotal trial for regulatory approval in both regions. The FDA has given Pluristem positive feedback on the proposed Phase III trial. The EU has accepted Pluristem's PLX-PAD cells for the treatment of CLI in its Adaptive Pathways pilot project, making PLX-PAD cells eligible for conditional market clearance following one pivotal trial. The EU is providing monetary support for the Phase III CLI trial through an approximately \$8 million grant from its Horizon 2020 program, which will cover a significant portion of the trial costs.

In Japan, Pluristem intends to conduct a 75-patient pivotal trial for PLX-PAD in the treatment of CLI, via Japan's accelerated regulatory pathway for regenerative medicine. Pluristem's strategic plan is to partner with a Japanese partner to conduct this study.

- **Heading Towards Pivotal Trial for Market Approval in the Treatment of ARS**

The National Institute of Allergy and Infectious Diseases (NIAID), a part of the U.S. NIH, is conducting dose selection studies in large animals to determine optimal dosing for Pluristem's PLX-R18 as a medical counter measure in the treatment of the hematologic components of Acute Radiation Syndrome (ARS). Upon determining the optimal dose, a pivotal trial in large animals is planned and the results will be used to support a Biologics License Application (BLA) submission of PLX-R18 for this indication under the Animal Rule regulatory pathway.

- **FDA Clearance for Phase I Trial in Hematologic Indication**

In January 2016, the U.S. FDA cleared Pluristem's Investigational New Drug (IND) application to begin its Phase I trial of PLX-R18 cells in the treatment of incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT).

- **Phase III Hip Surgery Trial in Preparation**

Pluristem intends to conduct 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 form of hip fracture. Pluristem has already submitted the study protocol to the EMA for a single pivotal trial in this indication through the Adaptive Pathways Project and plans to meet with the FDA later this year.

- **Global Phase II IC Trial Nearing Completion**

The Company expects to complete enrollment of all 170 patients in its global Phase II trial of PLX-PAD in the treatment of Intermittent Claudication (IC) within the next couple of months and to report trial results in 2017.

### **Financial Update:**

As of June 30, 2016 Pluristem had approximately \$33 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. During the fiscal year, Pluristem received a \$3.3 million grant to support clinical trials and R&D activities from the Israeli Innovation Authority of the Israeli Ministry of Economy and Industry. The Company's net cash used for operating activities was \$18.5 million during the fiscal year. After the end of the fiscal year, in August 2016, Pluristem was awarded a grant of approximately \$8 million from the EU's Horizon

2020 program to fund its upcoming Phase III trial of PLX-PAD in the treatment of CLI. 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., a late-stage biotechnology company, 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 Pluristem'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 for our cell therapies with respect to the treatment of peripheral artery disease and a range of hematologic and orthopedic indications, the description, timing and method of treatment and the proposed locations for our proposed clinical trials, our expectations regarding the possibility of accelerated regulatory approvals, our expected timing and ability to bring our cell therapies to market, our plans to partner with third parties to conduct studies and our anticipation of being well capitalized to conduct the clinical trials planned for initiation in the coming quarters as well ongoing R&D efforts to support development of future products. 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.

**Contact:**

Pluristem Therapeutics Inc.  
Karine Kleinhaus, MD, MPH  
Divisional VP, North America  
1-914-512-4109  
[karinek@pluristem.com](mailto:karinek@pluristem.com)