Pluristem Advances Towards Multinational Phase III Trial of PLX-PAD to Improve Recovery Following Surgery for Hip Fracture

- ***Clinical Advisory Board of leading orthopedic specialists and experts in rehabilitation met to discuss the design of the Phase III study prior to submission of the protocol to the FDA***
- ***Pluristem has already submitted the protocol to the European Medicines Agency for a single pivotal study in this indication***
- ***Phase II data showed PLX-PAD's strong muscle regeneration capacity following total hip replacement surgery***

HAIFA, ISRAEL, July 27, 2016 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced it intends to conduct a Phase III trial assessing its PLX-PAD cells in recovery following surgery for femoral neck fracture, which is the most common form of hip fracture. The trial protocol is now being designed by Pluristem and its Clinical Advisory Board (CAB), which is comprised of world-leading orthopedic surgeons, and experts in rehabilitation. Pluristem is planning to meet with the FDA later this year to discuss the Phase III protocol. The Company has already submitted this protocol to the European Medicines Agency (EMA) following consultation with the Adaptive Pathways Project Group. Pluristem's program in critical limb ischemia is already being developed via the Adaptive Pathways Project.

The Phase III study design builds upon positive data from a Phase II trial which showed that PLX-PAD cells induced significant muscle regeneration in patients who had undergone total hip replacement surgery. Patients treated with PLX-PAD at the time of surgery showed a 500% improvement in muscle force and a 300% improvement in muscle volume six months after surgery, as compared to the placebo group.

Muscle injury related to surgery, or to immobilization following surgery, may impact effective rehabilitation, and can lead to the loss of the ability to live independently, severe morbidity, and increased mortality. In the U.S., according to different sources, the lifetime prevalence of a hip fracture is 20% for women and 10% for men. Annual treatment costs in the U.S. are estimated to be between $10 to $15 billion, and are expected to rise because of the aging population.

"PLX-PAD's proven ability to regenerate muscles could play a critical role in improving the outcomes of the growing number of surgeries for femoral neck fracture," stated Pluristem Chairman and CEO Zami Aberman. "We are eager to move into Phase III trial in the U.S. and Europe in this important orthopedic indication. We look forward to working with the FDA and EMA to receive clearance to commence the trials."

Experts present at the meeting:

- Dr. Tobias Winkler. Charité - Universitätsmedizin Berlin, Germany
- Prof. Mohit Bhandari - McMaster University, Hamilton, Canada
- Dr. Kenneth Koval - Orlando Health Orthopedic Institute
- Prof. Laurie Burke - LORA Group, Maryland
- Prof. Jack Guralnik - University of Maryland
- Prof. Jay Magaziner - University of Maryland
- Prof. Thomas Einhorn - New York University

About Hip Fracture

Fractures of the hip are relatively common in adults and are associated with substantial morbidity and mortality. Most hip fractures occur in elderly individuals as a result of minimal trauma, such as a fall from the standing position. One-year mortality rates have been reported to range from 12 to 37 percent, and approximately half of patients are unable to regain their ability to live independently. In 2003, there were 310,000 individuals hospitalized with hip fractures in the U.S., according to data from the United States Agency for Healthcare Research and Quality (AHRQ), accounting for 30 percent of all hospitalized patients. As the U.S. population ages, the annual number of hip fractures is expected to increase significantly. The estimated cost for treatment of hip fracture is approximately $10 to $15 billion per year in the United States.

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 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 moving forward to a Phase III trial in the U.S. and Europe to asses PLX-PAD cells in recovery following surgery for femoral neck fracture, when we discuss working with the FDA and EMA to receive clearance to commence the trials and when we discuss that PLX-PAD’s proven ability to regenerate muscles could play a critical role in improving the outcomes of the growing number of surgeries for femoral neck fracture. 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.