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

HAIFA, ISRAEL, May 10, 2016 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today reported financial highlights for its fiscal third quarter ended March 31, 2016, and provided clinical and corporate updates.

"In the third quarter we achieved significant progress in the development of our PLX-R18 product, both as a treatment for a broad range of hematologic indications and as a medical counter measure in the treatment of Acute Radiation Syndrome (ARS). We received clearance from the U.S. Food and Drug Administration (FDA) to initiate a Phase I study in patients suffering from insufficient hematopoietic recovery following hematopoietic cell transplant. The National Institute of Allergy and Infectious Diseases (NIAID), a part of the U.S. National Institutes of Health (NIH), notified us that they will initiate studies in large animals to evaluate the dosing of PLX-R18 for the treatment of ARS. The first NIAID study is expected to start in the second quarter of 2016," stated Pluristem Chairman and CEO Zami Aberman.

"In Japan, we received two patents and licensed another key patent from Tokyo University that covers the treatment of ischemic diseases with placental cell therapy in Japan. We believe that our strong IP position in Japan will help in the completion of a PLX-PAD out-licensing deal with a Japanese pharma company," Aberman added. "Japan's Pharmaceuticals and Medical Devices Agency cleared the protocol for the trial we anticipate could lead to conditional marketing approval of PLX-PAD in the treatment of Critical Limb Ischemia, and Japanese pharmaceutical companies are expressing strong interest in cooperating with Pluristem. We have hosted a number of delegations at our factory in Israel, including the Japanese Ambassador, who visited in March."

Financial Update:
As of March 31, 2016, Pluristem had a strong balance sheet with over $38 million in cash and cash equivalents, bank deposits, restricted deposits and marketable securities. In addition, on May 9, 2016 the Company announced that it was awarded a $3.3 million grant from the Israeli government. The Company's net cash used for operating activities was $5.6 million for the third 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 development of future products.

Clinical and Corporate Highlights for the Third Quarter of Fiscal 2016 Include:

- U.S. FDA Clears Pluristem to Initiate Phase I Trial of PLX-R18

The 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 peripheral blood or umbilical cord blood transplants). An open-label Phase I trial is expected to begin in 2016, which 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 Fast Track Designation.

- U.S. NIAID to Initiate Dose Evaluation Studies of PLX-R18 for the Treatment of ARS

The NIAID will initiate studies in large animals to evaluate dosing for Pluristem's PLX-R18 as a medical counter measure in the treatment of the hematologic component of ARS. This condition is caused by exposure to extremely high levels of radiation, such as those that are due to a nuclear disaster. Once the optimal dose is determined in large animals, a pivotal trial could be conducted and the results could be used to support a Biologics License Application (BLA) submission of PLX-R18 for this indication under the Animal Rule regulatory pathway.

- Expands Intellectual Property Assets in Japan

The Japan Patent Office recently granted two additional patents to Pluristem. One addresses Pluristem's core technology of three-dimensional expansion methods for producing therapeutic cell products derived from placental or fat cells. Another covers the use of placenta-derived cells grown with this three-dimensional technology to treat disorders of the hematopoietic system, such as disorders caused by exposure to radiation or chemotherapy, and failed engraftment of hematopoietic stem cell transplants. Pluristem also licensed an important patent in Japan from TES Holdings Co., Ltd., a venture company derived from the University of Tokyo, to cover the treatment of ischemic diseases with placental cell therapy, thereby rounding out the Company's IP coverage in that country.

About Pluristem Therapeutics

Pluristem 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 require 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 expected timing for the initiation of a Phase I trial in patients suffering from insufficient hematopoietic recovery following hematopoietic cell transplant and the possibility of interim data analysis, when we discuss the possibility of a PLX-PAD out-licensing deal with a Japanese pharma company and other possible collaborations with us, when we discuss the possibility of a conditional marketing approval 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 development of future products, when we discuss our intention to pursue early market access for PLX-R18 in the United States via a Fast Track Designation, and when we discuss the possibility of conducting a pivotal trial and using its results to support a Biologics License Application submission of PLX-R18 for the treatment of the hematologic component of ARS under the Animal Rule regulatory pathway. 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.