Pluristem Announces Key Strategic Objectives for Development of PLX-R18 in Hematopoietic Indications

HAIFA, ISRAEL, March 24, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI) TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced the development strategy for PLX-R18, its second cell product.

Pluristem recently reported positive data from three independent preclinical studies of PLX-R18. Results from these trials, as well as those from nineteen prior studies conducted by the U.S. National Institutes of Health (NIH), Case Western University and Hadassah Medical Center, collectively suggest that PLX-R18 is safe and may significantly improve outcomes after bone marrow failure or hematopoietic cell transplantation. Data collected on mechanism of action show that PLX-R18 acts by reviving production of platelets and white and red blood cells in cases of severely damaged bone marrow, and may also accelerate engraftment of transplanted hematopoietic cells. With these capabilities PLX-R18 could potentially treat a broad range of indications related to bone marrow function which, taken together, constitute a substantial global market.

Pluristem's strategy for the development of PLX-R18 in the upcoming year is to progress with two initial indications in parallel. The Company expects to submit an application to advance into an FDA-approved clinical trial this year in order to determine if the product can treat insufficient engraftment of transplanted hematopoietic cells. These transplants are used in many settings including bone marrow ablation for certain types of blood cancers, and immune-related damage to bone marrow. Concurrently, Pluristem plans to continue working in partnership with the NIH in developing PLX-R18 as a potential treatment for acute radiation syndrome. In the upcoming months the Company expects to receive FDA guidance on the additional animal studies that would be required to approve PLX-R18 for use in Acute Radiation Syndrome (ARS) under the Animal Rule regulatory pathway. This pathway does not require human efficacy trials. Pluristem also anticipates that the NIH may continue to support and conduct trials to determine if PLX-R18 can bring about the recovery of the hematopoietic system in patients with acute radiation syndrome.

The work on PLX-R18 is being done alongside the ongoing development of PLX-PAD, Pluristem's first product. PLX-PAD is currently being studied in a multinational phase II trial in intermittent claudication, and a phase I trial in pulmonary arterial hypertension; the latter trial is partnered with United Therapeutics. The company plans to initiate

advanced trials for PLX-PAD in critical limb ischemia (CLI) via the accelerated regulatory pathways now available in Japan and Europe. The two distinct PLX products were designed to have different secretion profiles in order to target different indications. The secretion profiles differ because the two products are produced by expanding placental cells in different, specifically tailored, three-dimensional micro-environments within patented bioreactors, and by selecting maternal cells from term placenta to make PLX-PAD, and fetal cells from term placenta to make PLX-R18.

About Hematopoietic Cell Transplantation and PLX-R18

Hematopoietic stem cells, which can be obtained from bone marrow, umbilical cord blood or peripheral blood, are transplanted into patients with damaged, dysfunctional or ablated bone marrow in order to take over the role of generating white and red blood cells and platelets. Successful engraftment of transplanted hematopoietic cells can take an average of approximately three to four weeks, but in some cases engraftment can be delayed for many months, or remain insufficient. During that time patients who are not producing sufficient numbers of platelets, white cells and red cells, are at substantial risk of death from hemorrhage, infection, or even severe anemia. Although there are multiple indications for which recovery of all three blood cell lines is required for patient survival, the Company is aware of no single treatment on the market at this time that can stimulate production of more than one type; separate products can stimulate either white cell or red cell production, but not both. In addition, the Company is aware of no satisfactory option to stimulate production of platelets in the context of myeloablative chemotherapy or hematopoietic cell transplantation, which account for much of the platelet use in the treatment of malignant disease. Building on the positive preclinical data showing that PLX-R18 can significantly increase platelet and blood cell production, Pluristem believes that PLX-R18 may become a transformative treatment option for patients with insufficient engraftment of hematopoietic stem cells.

About Acute Radiation Syndrome (ARS) and PLX-R18

The NIH is studying PLX-R18 as a potential treatment of the hematologic component of ARS. The syndrome is caused by exposure to dangerously high levels of radiation, such as could occur in a nuclear catastrophe, and incorporates severe damage to the bone marrow's ability to produce blood cells and platelets, as well as lethal damage to other systems and organs. Damage to the bone marrow quickly makes victims vulnerable to life-threatening hemorrhage, infection and anemia. In an FDA meeting anticipated in the upcoming months, the Company expects to discuss the additional studies that would be required for approval of PLX-R18 for ARS under the FDA's Animal Rule. Pluristem believes that an agreement with the FDA on the next steps needed for development of PLX-R18 in ARS could encourage the NIH to support the required trials. If the Company attains FDA approval of PLX-R18 for treatment of ARS, the next stage would be to potentially contract with the U.S. government to stockpile the treatment for use in case of a nuclear disaster. Ongoing use of PLX-R18 in other hematologic indications would make stockpiling for ARS a cost-effective option for the government. PLX-R18 could be stored, used and replaced for other indications so that the government would not have to

maintain a full supply of the product on its own. PLX-R18 cells are potentially suitable for the rapid initiation of treatment of large populations because they do not require tissue matching prior to administration, and can be administered with an ordinary intramuscular injection to generate a systemic effect, as is done with penicillin or many vaccines. Pluristem expects that additional data generated in NIH trials will continue to support ongoing development of PLX-R18 in other hematologic indications.

About the mechanism of action of PLX-R18

Studies on the mechanism of action of PLX-R18 cells, which have been conducted at several laboratories and by the NIH, collectively suggest that PLX-R18 cells act via integrated secretion of many specific therapeutic proteins in response to chemical signals from a damaged hematopoietic system, and that over time these proteins stimulate: 1) the recovery of the bone marrow's microenvironment; 2) the renewal and differentiation of those progenitor cells that produce the body's red and white cells and platelets; 3) the migration of those cells into the blood stream to function. This understanding of the mechanism of action of PLX-R18 cells underpins Pluristem's choice of the first two hematologic indications, and will continue to drive strategic decisions regarding additional indications.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cells are grown using the Company's proprietary three-dimensional expansion technology and are an "off-the-shelf" product that requires no tissue matching prior to administration.

Pluristem has a strong intellectual property position, Company-owned, GMP-certified manufacturing and research facilities, strategic relationships with major research institutions, and a seasoned management team. For more information visit www.pluristem.com, the content of which is not part of this press release.

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, forward-looking statements are used in this press release when we discuss that PLX-R18 is safe and may significantly improve outcomes after bone marrow failure or hematopoietic cell transplantation, PLX-R18's potential to treat a broad range of indications related to bone marrow function which, taken together, constitute a substantial global market, when we discuss our strategy, plans and clinical trials for the development of PLX-R18 in the upcoming year, when we discuss submitting an application to advance into an FDA-approved clinical trial this year in order to determine if the product can treat insufficient engraftment of transplanted hematopoietic

cells, when we discuss our plans to continue working in partnership with the NIH in developing PLX-R18 as a potential treatment for acute radiation syndrome, when we discuss our expectation to receive in the upcoming months FDA guidance on the additional animal studies that would be required to approve PLX-R18, when we discuss our belief that an agreement with the FDA on the next steps needed for development of PLX-R18 in ARS could encourage the NIH to support the required trials, when we discuss our plans to potentially contract with the U.S. government to stockpile the treatment for use in case of a nuclear disaster if the Company attains FDA approval of PLX-R18 for treatment of ARS, when we discuss continuous support, clinical trials and data generated by the NIH with respect to PLX-R18, when we discuss our primary strategic focus in the upcoming year to initiate advanced trial in critical limb ischemia (CLI) via the rapid regulatory pathways now available in Japan and Europe, or when we discuss our belief that PLX-R18 may become a transformative treatment option for patients with insufficient engraftment of hematopoietic stem cells. 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 surgical 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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