Pluristem Receives Clearance from Germany to Initiate its Multinational Phase III Trial in Critical Limb Ischemia Targeting Early Conditional Marketing Approval

- *PLX-PAD cells could potentially obtain early conditional marketing approval in Europe via the Adaptive Pathways pilot project based on positive interim efficacy data from first 125 patients*
- *This approval joins those from the U.S. FDA and U.K. for this 250-patient Phase III Trial*
- *Germany is Western Europe's largest market for Critical Limb Ischemia*
- *Enrollment expected to commence in the first half of 2017*

HAIFA, ISRAEL, January 17, 2017 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that Germany's health regulatory agency, the Paul Ehrlich Institute (PEI), has cleared Pluristem to begin enrollment in Germany for its pivotal Phase III trial of PLX-PAD cells to treat Critical Limb Ischemia (CLI) in patients who are unsuitable for revascularization. The trial was recently cleared by the United States' Food and Drug Administration (FDA) and the United Kingdom's Medicines & Healthcare products Regulatory Agency (MHRA).

PLX-PAD cells have been selected by the European Medicines Agency (EMA) to be developed for CLI via the Adaptive Pathways pilot project. Under this regulatory pathway, the multinational Phase III trial may potentially lead to early marketing approval of PLX-PAD for CLI in Europe, based on interim efficacy data from the first 125 patients that have completed a follow-up of 12 months. Data from the entire 250 patients will be submitted to the U.S. FDA for a Biologics License Application (BLA) targeting commercialization, and to the EMA to apply for full marketing approval.

"The potential for early marketing approval is an important achievement for us, and we are glad that we may help bring hope to CLI patients with no good treatment options. It is gratifying to see that regulatory authorities around the world are working to accelerate patient access to innovative treatments for medical conditions, such as CLI, that are unmet medical needs," stated Pluristem Chairman and CEO, Zami Aberman.

The global Phase III trial will evaluate PLX-PAD cells in the treatment of CLI in a double-blind, randomized, placebo-controlled trial. An estimated 250 patients with CLI Rutherford Category 5, who are unsuitable candidates for revascularization, will be enrolled. Patients will be treated with 300 million cells or placebo, injected twice intramuscularly (IM) two months apart. The primary endpoint will be time to amputation or death, allowing for a survival analysis which enables collection of more data during the trial thereby significantly reducing the number of patients needed, to allow statistically significant results from a trial of this size.

About Critical Limb Ischemia

In CLI, fatty deposits block arteries in the leg, leading to greatly reduced blood flow. This causes leg pain at rest, non-healing ulcers and gangrene. Patients with CLI are at high risk for limb amputation and death within a year of diagnosis. While some conservative treatments exist to relieve pain, and provide localized ulcer care, most patients will ultimately need a revascularization procedure. CLI patients who cannot undergo revascularization procedures are left with poor treatment options, and have a severe unmet medical need. With over 700,000 citizens suffering from critical limb ischemia, Germany represents the single largest Western European market, as per the Sage group (2010). This reflects the fact that Germany has the highest regional prevalence of diabetes, as well as the greatest number of elderly citizens, which are major risk factors for CLI.

About the Adaptive Pathways Pilot Project

The purpose of EMA's Adaptive Pathways pilot project is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options. The pathway is open to clinical programs in early stages of development only. After a therapy is selected for the program, the Adaptive Pathways group conducts high level discussions and provides guidance to the applicant regarding the formal regulatory processes that precede a trial, targeting early approval and further expansion of the indications.

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 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 relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss the timing of patient enrollment in our Phase III CLI trial, the potential for expedited approval of PLX-PAD cells for the treatment of CLI in Europe by the EMA, the review of patient data from the Phase III CLI study by the EMA, the potential for the efficacy data as a result of the Phase III CLI trial to support Pluristem's Biologics License Application and when we discuss the potential for PLX-PAD cells to treat CLI. 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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