Pluristem's Pivotal Phase III Critical Limb Ischemia Trial Approved by UK Regulatory Agency

- ***Pluristem expects to begin patient enrollment in the UK in first half of 2017***
- ***The trial will recruit in the U.S. and EU***

HAIFA, ISRAEL, November 1, 2016-- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that the United Kingdom's Medicines & Healthcare Products Regulatory Agency (MHRA) has cleared Pluristem's application to begin the pivotal Phase III trial of PLX-PAD cells in the treatment of Critical Limb Ischemia (CLI) for patients who are unsuitable for revascularization. Pluristem's CLI program was previously selected by the European Medicines Agency (EMA) for its Adaptive Pathways pilot project, which may allow for conditional marketing approval after a single pivotal Phase III trial.

The multinational Phase III trial will be conducted in the U.S. as well as Europe. The U.S. Food and Drug Administration (FDA) has previously given positive feedback on the trial protocol in a pre-Phase III interaction. Pluristem's intention is to file a request for marketing authorization in the U.S. and in Europe following a successful completion of this 250-patient trial.

"Pluristem is very pleased to receive clearance to commence our pivotal Phase III CLI trial in the United Kingdom. We are eager to move forward to confirm efficacy of PLX-PAD cells in CLI, and anticipate receiving similar authorizations from additional regulators in Europe and the United States. Executing on an accelerated clinical development timeline, we anticipate commencing patient enrollment in the first half of 2017," stated Pluristem Chairman and CEO, Zami Aberman. "We believe cell therapy holds great promise for patients with difficult to treat, life threatening conditions, such as CLI, and hope to play an important role in improving their health outcomes."

The 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 that is well powered to deliver 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 local ulcer care, most patients will ultimately need a revascularization procedure. Many, however, are not suitable candidates for revascularization, and have high rates of major amputations (up to 40% at six months from diagnosis).

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 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 design and endpoints of our Phase III trial of PLX-PAD cells in the treatment of CLI, the expected timing for commencing enrollment, and our plan to conduct the trial in the U.S. and in Europe; when we discuss our intention to file a request for marketing authorization in the U.S. and in Europe following a successful completion of the trial; when we discuss our anticipation to receive similar authorizations from additional regulators in Europe and the U.S.; and when we discuss the potential of cell therapy to treat life threatening conditions and improve health outcomes. 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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