U.S. FDA Grants Fast Track Designation to Pluristem's PLX-PAD for the Treatment of Critical Limb Ischemia (CLI)

- ***Pluristem's Ongoing Phase III CLI trial has been selected for accelerated approval pathways in both the U.S. and Europe***
- ***Fast Track Designation allows for expedited review of drugs to treat serious conditions with unmet medical need***

HAIFA, ISRAEL, September 18, 2017 -- Pluristem Therapeutics, Inc. (NASDAQ:PSTI; TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to the company's ongoing Phase III study of PLX-PAD cells for the treatment of Critical Limb Ischemia (CLI) in patients ineligible for revascularization. The FDA's Fast Track Designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and unmet medical needs. With Fast Track Designation, there is an increased possibility for a priority review by the FDA of PLX-PAD cells for the treatment of CLI.

"We are extremely pleased with the FDA's decision to grant Fast Track Designation to PLX-PAD in the treatment of CLI. Up to 40% of patients with CLI are ineligible for revascularization and are at high risk of amputation and death within the first year of diagnosis. This disease takes a heavy toll on patients and their families, while the cost of treating CLI in the U.S. alone is estimated at over $25 billion per year. We are working tirelessly to provide a cell therapy that will address this severe unmet medical need" said Zami Aberman, Chairman and Co-CEO of Pluristem.

"Regulators in some of the largest healthcare markets in the world are now in alignment regarding the need for accelerated approval pathways for our cell therapy product in the treatment of CLI. Programs like the Fast Track Designation offer real hope for patients battling this disease and we look forward to accelerating the path to market for PLX-PAD," stated Pluristem President and Co-CEO, Yaky Yanay.

Pluristem's Phase III CLI study is ongoing and actively enrolling patients in the U.S. and Europe. The European Medicines Agency (EMA) has included PLX-PAD in its Adaptive Pathways program. Positive results from an interim analysis following treatment of half (125) of the study's population may lead to early conditional marketing authorization. In Japan, the Pharmaceuticals and Medical Devices Agency (PDMA) has accepted PLX-PAD for the treatment of CLI into its accelerated regulatory pathway for regenerative therapies and has agreed on the design of a single study (N=75) that may lead to early conditional marketing approval and reimbursement.

About CLI

In Critical Limb Ischemia (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 immediate risk for limb amputation and death. It is estimated that 5-6 million people in the U.S. and Europe suffer from CLI, and this number is projected to grow with the increasing rate of diabetes. While some non-surgical treatments exist to relieve pain and provide local ulcer care, most patients will ultimately need revascularization with vascular bypass surgery or an endovascular procedure to try to prevent major limb amputation and prolong survival. However, up to 40% of patients are unsuitable for revascularization and experience up to a 40% amputation rate at 1 year.

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, and is entering late-stage trials in several indications. PLX cell products release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders, and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. 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, Pluristem is using forward-looking statements when its discusses that the Fast Track Designation of its Phase III study of PLX-PAD cells for the treatment of CLI may increase the possibility of a priority review by the FDA, its belief that regulators in some of the largest healthcare markets in the world are now in alignment on the need for accelerated approval pathways for its cell therapy product in the treatment of CLI, that positive results from an interim analysis of its Phase III CLI study in Europe may lead to early conditional marketing authorization and that its single study in Japan, which has been approved by the PDMA, may lead to early conditional marketing approval and reimbursement in Japan. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem’s products may not be approved by regulatory agencies, Pluristem’s technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem’s process; Pluristem’s products may wind up being more expensive than it anticipates; 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; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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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