Pluristem's Phase III Study of PLX-PAD Cells for the Treatment of Critical Limb Ischemia Cleared by U.S. FDA

HAIFA, ISRAEL, January 10, 2017 -- Pluristem Therapeutics Inc. (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that the Company's Phase III study of its PLX-PAD cells in the treatment of critical limb ischemia (CLI) was cleared by the U.S. Food and Drug Administration (FDA). Pluristem's strategy is to use this single multinational Phase III study to support the submission of a biologics license application (BLA) to the FDA for marketing approval. Pluristem expects to begin enrolling patients in its Phase III study in both the U.S. and Europe during the first half of 2017.

"We are excited to have received FDA clearance to initiate our Phase III study for this very important indication. Our PLX-PAD product candidate provides hope for a new, effective treatment and a better quality of life for millions of CLI patients. Pluristem is committed to advancing its peripheral artery disease programs in CLI and intermittent claudication (IC) worldwide," stated Pluristem Chairman and CEO Zami Aberman.

"The use of a time-to-event endpoint in our CLI trial, as is employed in many advanced clinical trials, will allow us to gather more data during the trial thereby significantly reducing the number of patients needed. Data from previous clinical studies have shown that, by increasing tissue perfusion, PLX-PAD may improve the healing of wounds in CLI patients, and could allow for significant delays in events of amputation or death in the treated group," Mr. Aberman concluded.

In CLI, fatty deposits block arteries in the leg, leading to greatly reduced blood flow, pain at rest, non-healing ulcers, and gangrene. Patients with CLI are at an immediate risk for limb amputation and death. With poor treatment options, CLI patients who cannot undergo revascularization procedures have a severe unmet medical need.

Pluristem's Phase III CLI study will be a double blind, randomized, placebo controlled trial of about 250 patients with CLI Rutherford Category 5 who are unsuitable for revascularization. At an estimated 40 clinical sites in the U.S. and Europe, patients will be treated with 300 million PLX-PAD cells or placebo, injected twice intramuscularly (IM), with the second injection administered two months after the first. The primary endpoint is time to amputation or death. The European Medicines Agency (EMA) previously selected the PLX-PAD program in CLI for

its Adaptive Pathways pilot project, which may allow for conditional marketing approval after a single pivotal study.

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 different cell products each release their own 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. No tissue matching is required to administration of PLX cell products.

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 our multinational Phase III study in CLI, the timing of patient enrollment for the trial, how this trial can support our BLA for marketing approval and when we discuss the potential for PLX-PAD cells to treat CLI and the potential impact such treatment could have in improving patient healing and quality of life. 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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