Lead Physicians in Pluristem's Pivotal Study in Critical Limb Ischemia Publish Peer-Reviewed Paper

Paper appears in the European Journal of Vascular and Endovascular Surgery and highlights the study's design rationale and the potential impact of PLX cells in the treatment of CLI

HAIFA, Israel, May 15, 2019 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, announced the publication of a peer-reviewed article in the *European Journal of Vascular and Endovascular Surgery (EJVES)* titled "PLX-PAD Cell Treatment of Critical Limb Ischemia: Rationale and Design of the PACE Trial." The article, written by key physicians conducting the pivotal study, presents the Company's ongoing Phase III study evaluating PLX-PAD cell therapy for the treatment of critical limb ischemia (CLI). The pivotal study is also designed to measure long-term outcomes and collect parameters to assess the potential economic benefit of this kind of treatment. Additionally, an invited commentary that also appears in *EJVES* lends strong support for the study's design and potential impact.

The paper cites the significant need that exists for new and effective CLI treatment options when revascularization is not an alternative, and the shortcomings and differentiation from other therapies that have failed to demonstrate meaningful benefits in controlled clinical studies to date. Pluristem's PLX-PAD cell therapy has been successfully evaluated in two Phase I CLI studies, with additional supportive data from a Phase II intermittent claudication (IC) study. In these studies, PLX-PAD cells have demonstrated a favorable safety profile as well as significant pain reduction, an increase in tissue perfusion, a reduction in surgical events and significant improvement in HbA1c (blood glucose control) and CRP levels (blood test marker for inflammation in the body).

"Several therapies have been tested to meet the medical need of these patients and have not succeeded in demonstrating meaningful benefits to date," commented Prof. Lars Norgren, Department of Surgery, Faculty of Medicine and Health, Örebro University, Sweden and lead author of the paper. "From an immunological point of view, it has been shown that treatments using the patient's own cells, and in particular those with cardiovascular risk factors or CLI, are reduced in functionality. One reason Pluristem's PLX-PAD cell therapy is so desirable is that the young healthy placenta cells being used in the therapy are of a better quality and have the potential for higher efficacy than previously seen."

"CLI is a widely recognized disease leading to losses of limbs. With the aging of the world's population, the incidence of this problem continues to increase," commented Dr. John Lantis, MD, Vice Chairman of the Department of Surgery and Chief of Vascular and Endovascular Surgery

at Mount Sinai West and a co-author of the paper. “For these patients who do not have an option for revascularization, and those for whom the risks of intervention outweigh the benefits, we need another option. An intervention focused on office-based injections that could grow new blood vessels could definitely be a game changer for many patients. It is exciting to be a part of a study that may truly give us a new medical option.”

“We are grateful for the opportunity to bring CLI patients closer to a medical solution and we thank those who are participating in the study, as well as the investigators who are working to efficiently advance this important late-stage study,” said Zami Aberman, Chairman and Co-Chief Executive Officer of Pluristem. “Our goal is to make this potentially ground-breaking treatment available to CLI patients, an underserved patient population, as quickly as possible.”

Pluristem recently completed enrollment of half of the study’s population (n=123). An interim analysis may be allowed following a 12-month follow-up period and could support an application for conditional marketing approval in Europe, under the European Adaptive Pathways Program. The Company’s PLX-PAD CLI program has also been granted Fast Track Designation, and selected for an Expanded Access Program (EAP), by the U.S. Food and Drug Administration (FDA) as well as awarded a €7.6 million grant from the European Union’s Horizon 2020 Research and Innovation Program.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product and is currently conducting late stage clinical trials in several indications. PLX cell product are believed to 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; a Company-owned and operated GMP-certified manufacturing and research facility; 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 it discusses that its PLX-PAD cell therapy is desirable because placenta cells are of a better quality and have the potential for higher efficacy, that an intervention focused on office-based injections that could grow new blood vessels may be a game changer for many patients and could provide a new medical option, that Pluristem’s goals are to make the PLX-PAD cell therapy available for patients as quickly as possible and that Pluristem may be allowed to provide an interim analysis of its PLX-PAD pivotal study within a 12 month follow up period which may support an application for conditional marketing approval in Europe under the European Adaptive Pathways Program. 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.

Contact:
Efrat Kaduri
Director of Business, Investor and Public Relations
972-74-7108600
efratk@pluristem.com