



New Findings from Pluristem's Phase II IC study:

PLX-PAD Cells Significantly Improves Blood Glucose Control (HbA1c) and Reduce Chronic Inflammation

Additional data from Pluristem's Phase II IC study were presented at the 2018 American Heart Association Scientific Sessions

HAIFA, Israel, November 12, 2018 - [Pluristem Therapeutics Inc.](http://www.pluristem.com) (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that the Company presented additional data from its Phase II clinical study evaluating PLX-PAD for the treatment of Intermittent Claudication (IC) at the 2018 American Heart Association Scientific Sessions in Chicago. The data were presented by Prof. Norbert Weiss, MD, Director of the Vascular Center at the Technical University of Dresden, Germany, and the lead European Principal Investigator for the Phase II IC study.

Among the study findings:

- Additional analysis of the Phase II IC data confirmed the optimal dosing regimen of PLX-PAD in the treatment of peripheral arterial diseases (PAD) - two administrations of 300 million cells, each originating from a different donor. This is also the treatment regimen being administered to patients in the Company's ongoing multinational Phase III study in Critical Limb Ischemia (CLI), a more severe stage of PAD.
- Patients treated with PLX-PAD at the optimal dosing regimen showed statistically significant improvement (effect size=42.0%, p=0.043) in maximum walking distance (MWD) at 52 weeks across all sites (U.S, Europe, Israel and South Korea), nationalities, gender and ethnicity as compared to placebo. These patients also experienced no revascularization events at 65 weeks as compared to 12% occurrence in the placebo group.
- An additional analysis of the data showed patients treated with PLX-PAD at the optimal dosing regimen demonstrated a significant (p= 0.0012) decrease of 48% in C-reactive protein (CRP) at 65 weeks, as compared to 95% increase in the placebo group. High levels of CRP, a protein found in blood plasma, is associated with inflammation which is associated with PAD.
- Moreover, these patients also experienced a statistically significant relative reduction of 7.77 (mmol/mol) in Hemoglobin A1C (HbA1c) at 65 weeks compared to placebo (p=0.0155). HbA1c measures the amount of blood sugar (glucose) attached to hemoglobin. A reduction in HbA1c

indicates better glucose control in patients and is the most commonly used measurement to evaluate treatment efficacy in diabetics.

- PLX-PAD treated patients showed good safety profile in the study as well as a reduction in the incidence of adverse events including malignancies, respiratory events and cardiac disorders.

“We are very encouraged with the results and additional findings seen in this study. PAD patients, especially those suffering from CLI, often display high level of inflammation and, as seen within our IC study, most are diabetic,” commented Prof. Weiss. “The data we presented at the AHA suggest that PLX-PAD may play a meaningful role in lowering inflammation and maintain better glycemic control reflecting the potential of this non-surgical cell-based therapeutic to address key unmet needs of PAD and the associated co-morbidities.”

“This study was important in confirming the design of our ongoing Phase III trial evaluating PLX-PAD for the treatment of CLI, and we are optimistic that these promising results will be reproducible in larger patient populations,” said Zami Aberman, Chairman and Co-Chief Executive Officer of Pluristem. “The recent findings provide comprehensive understanding of PLX-PAD cells mechanism of action in PAD patients by supporting angiogenesis, reducing inflammation and lowering the average glucose levels of this patients. The recent FDA approval of the expanded access program in CLI, together with the multiple special regulatory pathways that we have been granted in the U.S. and Europe, and the significant funding that we have received for this project to date, justify our growing enthusiasm for PLX-PAD as a potential new and groundbreaking treatment for PAD. We look forward to Phase III data as we work to introduce this treatment as an innovative solution for PAD patients.”

Initial topline results from this Phase II IC study were previously [announced](#) by the Company in June 2018.

About Pluristem’s Phase II IC Study

Pluristem's Phase II IC study was designed to evaluate the safety, efficacy and optimal dosing regimen for PLX-PAD cells in patients with IC Rutherford categories 2-3. Enrollment took place at 28 clinical sites in the U.S., Germany, South Korea and Israel. The 172 patients in the study were randomized into four treatment groups: two administrations of 300 million PLX-PAD cells (“main efficacy group”); two administrations of 150 million PLX-PAD cells; two administrations of placebo; or one administration of 300 million PLX-PAD cells followed by placebo. In each of these study arms, the two administrations were given intramuscularly (IM), 3 months apart. The primary efficacy endpoint was the change from baseline in maximal walking distance (MWD) at 52 weeks compared to placebo. The key secondary endpoint was the change from baseline in MWD at 52 weeks compared to placebo, in patients treated with 2 doses of PLX-PAD originating from different donors (Pluristem’s proprietary Bio-Therapeutic approach). Other endpoints included risk of revascularization and other hemodynamic and clinical outcome measures.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX 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 it discusses the potential of PLX-PAD to play a meaningful role in lowering levels of CRP and HbA1c and to address key unmet needs of PAD, the ability to reproduce the results of clinical trials in larger patient populations and the potential for PLX-PAD to be a new and groundbreaking treatment for PAD. 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

Contact:

Efrat Kaduri
Head of Investor and Public Relations
972-74-7108600
efratk@pluristem.com

Karine Kleinhaus, MD, MPH
Divisional VP, North America
1-914-512-4109
karinek@pluristem.com