



Pluristem Reports Positive Top-Line Results from Its Multinational Phase II Intermittent Claudication Study

PLX-PAD treatment reduced risk of revascularization and improved patients' mobility.

Study validates the design of Pluristem's ongoing Pivotal Phase III study in Critical Limb Ischemia (CLI)

HAIFA, Israel, June 12, 2018 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, today announced positive top-line results from its multinational Phase II clinical study of PLX-PAD cells in the treatment of Intermittent Claudication (IC). PLX-PAD treatment reduced Incidence of revascularization and improved patients' mobility. Study results also validate the design of Pluristem's ongoing Pivotal Phase III study in CLI, a more severe stage of peripheral arterial disease (PAD) and confirm Pluristem's proprietary Bio-Therapeutic approach.

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 placentas (Pluristem's proprietary Bio-Therapeutic approach). Other endpoints included risk of revascularization and other hemodynamic and clinical outcome measures.

Top Line Results:

- Patients treated with 2 administrations of 300 million PLX-PAD cells showed statistically significant improvement ($p=0.0008$) in MWD as compared to baseline at 52 weeks.
- Key primary efficacy endpoint, improvement in MWD as compared to placebo, in analysis by country, showed best results with statistically significant improvement (effect size= 51.1%, $p=0.015$) in U.S patients ($n=73$) treated with 2 administrations of 300 million PLX-PAD cells.
- Key secondary efficacy endpoint, improvement in MWD following administration of 2 doses of 300 million PLX-PAD cells originating from different placentas, showed statistically significant improvement at 52 weeks (effect size= 42.0%, $p=0.043$) as compared to placebo. These patients also demonstrated a statistically significant improvement (effect size= 83%, $p=0.0007$) in MWD at 52 weeks as compared to baseline.
- Revascularization risk was reduced by 49% (Hazard ratio = 0.51) in the main efficacy group at week 65. Patients receiving 2 administrations of PLX-PAD cells originating from different placentas were "revasc-free" (no revascularization events) at week 65.
- IM administration of PLX-PAD cells was safe and well tolerated.

Validation of study design in ongoing Pivotal Phase III study in Critical Limb Ischemia (CLI):

- Dose confirmation- Study results demonstrated dose of 300 million PLX-PAD cells as the optimal dose for treatment of PAD

- Two administrations of 300 million PLX-PAD cells demonstrated a statistically significant superior effect ($p=0.0331$) compared to a single administration of 300 million PLX-PAD cells in MWD at week 52, suggesting that in chronic indications such as PAD a second treatment may be required to significantly improve the clinical outcome.
- Pluristem's proprietary Bio-Therapeutic approach of using cells originating from different placentas for each administration, as implemented in the CLI pivotal Phase III clinical study, was shown to generate a superior therapeutic effect.

"We are highly encouraged by the results seen in the study. The option of treating peripheral artery diseases like IC and CLI through IM injections of PLX-PAD cells is promising, and an important outcome, demonstrating the potential ability to implement regenerative medicine advanced technologies in cardiovascular diseases. We look forward to the CLI pivotal study results that may demonstrate the ability of Pluristem's cell therapy to improve patient outcomes and create economic benefits for the healthcare systems," stated Dr. Manesh Patel, Chief of the Division of Cardiology at Duke University Health System, and the lead principle investigator (PI) for the U.S. Phase II IC study.

"These promising results demonstrate a clinically meaningful treatment effect. Finding a non-surgical medical solution for PAD, especially in patients who are unsuitable for revascularization, has proven to be one of the biggest medical challenges in recent years. These study results are highly encouraging and suggest that PLX-PAD cells may be the answer for both PAD patients and physicians seeking effective medical solutions," commented Prof. Norbert Weiss, MD, Director of the Vascular Center at the Technical University of Dresden, Germany, and the lead PI for the European Phase II IC study.

"We are very pleased with the study results that may bring hope to millions of patients worldwide suffering from peripheral artery diseases," stated Pluristem Chairman and Co-CEO Zami Aberman. "These results suggest that PLX-PAD cells may be efficacious in the treatment of PAD and could significantly reduce the need for invasive procedures in these patients. Furthermore, these results provide important validation to our ongoing pivotal Phase III study in CLI in terms of dose selection, dual-dosing administration regimen and the superiority of our proprietary Bio-Therapeutic approach we have developed in the last few years of using different placentas when more than one treatment is required. The unique PLX platform and manufacturing processes we developed enable us to confirm donor-to-donor and batch-to-batch comparability and achieve optimal clinical benefits."

About Peripheral Artery Diseases (PAD)

Peripheral Arterial Disease (PAD) is caused by fatty deposits in leg arteries that obstruct blood flow. Risk factors include smoking, diabetes, heavy weight, cardiovascular problems and hypertension. An earlier stage of PAD is Intermittent Claudication (IC) with symptoms of leg pain and weakness brought on by exercise, with resolution of the symptoms following rest. IC can progress to Critical Limb Ischemia (CLI) when patients suffer from severe pain at rest, skin wounds, tissue necrosis and poor quality of life with a high risk of leg amputation and death. PAD affects 4-12% of people aged 55-70 years and 15-20% of people aged over 70 years. The frequency of lower extremity artery disease is strongly age-related, rising steeply after 50 years of age. PAD afflicts about 20 million U.S. citizens, 28 million Western Europeans and 42 to 60 million Chinese citizens.

Pluristem's Phase III study in Critical Limb Ischemia (CLI), was cleared by the U.S Food and Drug Administration (FDA) and European Medicines Agency (EMA) and is recruiting patients (n=246) in the U.S. and Europe.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical study data in multiple indications for its patented PLX cells and is entering late-stage studies 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 outcome of the IC study's impact on its CLI study, including dosage administration, that the study result may bring hope to millions of patients worldwide suffering from peripheral artery diseases and that the study results suggest that PLX-PAD cells may be efficacious in the treatment of PAD and could significantly reduce the need for invasive procedures in these patients. 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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