



## **Pluristem Completes Enrollment of 150 Patients in Phase II Intermittent Claudication Trial**

- *Trial expands to randomize 20 more patients to receive two injections per patient*
- *Data release on track for 2017*

**HAIFA, ISRAEL, May 16, 2016** - [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI , TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced it has completed the planned enrollment of 150 patients in a global Phase II trial of its PLacental eXpanded, PLX-PAD, cells for the treatment of intermittent claudication (IC), a peripheral artery disease (PAD). The double blind, randomized, placebo controlled trial enrolled 50 patients since last October in the U.S., Germany, Israel, and South Korea.

Pluristem has expanded the trial to enroll 20 additional patients to be randomized in order to preserve the study's original design to administer two injections to each of 150 patients. Twenty of the 150 patients originally enrolled did not complete the trial with two injections. Previous findings in clinical and preclinical studies of PLX cells demonstrated the superior efficacy of two injections vs. a single injection in certain indications.

"We have seen a significant increase in the enrollment rate in the last six months, and I eagerly anticipate the final results of this study. As there is significant suffering of patients with peripheral artery disease, the medical field must advance in offering treatment strategies in addition to revascularization or supervised exercise training, which is not suitable for all patients," stated the study's Principal Investigator, Prof. Dr. Norbert Weiss, of the Dresden Division of Angiology, Center for Vascular Medicine and Department of Internal Medicine, University Hospital Carl Gustav Carus, Technische Universität Dresden in Germany.

"In the last two years we significantly advanced our understanding of the mechanisms of action of PLX cells, and established the importance of repeat injections to stimulate tissue regeneration in certain acute and chronic indications. Based on our recruitment rate in the last half year, we anticipate quickly completing enrollment of the additional patients," said Pluristem Chairman and CEO Zami Aberman.

## **About Intermittent Claudication**

IC is a subset of peripheral artery disease, caused by atherosclerosis of the lower extremity arteries. IC is characterized by muscle pain, cramping, numbness or a sense of fatigue, classically in the calf muscle, which occurs during walking or similar exercise and is relieved by a period of rest. The prevalence of IC in the United States alone is approximately 14 million patients, representing a cost of approximately \$2.5 billion annually to the national health care system.

## **About the Study**

Pluristem's Phase II trial is evaluating the safety and efficacy of two doses of PLX-PAD cells versus placebo, administered via intramuscular injections. The study protocol is now comprised of approximately 170 patients with IC, Fontaine class IIb, Rutherford category 2-3. In addition to the primary efficacy endpoint of change in the maximal walking distance from baseline during an exercise treadmill test, secondary endpoints of the study are hemodynamic and quality of life measurements. Safety parameters are also being assessed.

## **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 cells release a 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. They are off-the-shelf, requiring no tissue matching prior to administration.

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 forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and federal securities laws. For example, we are using forward-looking statements when we discuss our plan to enroll 20 additional patients to our Phase II trial of our PLX-PAD cells for the treatment of IC, the expected enrollment rate and timing of completion of the enrollment. 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.