



Pluristem Completes Patient Enrollment in a Large Multinational Phase II Trial in Intermittent Claudication

- *Top line results from the 172-patient trial to be reported in early 2018*
- *Data to support Pluristem's planned Biologics License Application for marketing approval of PLX-PAD in the U.S. and Europe*
- *14 million people in the U.S. are treated for IC, at a cost of approximately \$2.5 billion annually to the health care system*

HAIFA, ISRAEL, January 12 2017 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that it has completed enrollment of all 172 patients in a multinational Phase II trial of its PLX-PAD cells in the treatment of intermittent claudication (IC), a peripheral artery disease (PAD). Enrollment took place at 30 clinical sites in the U.S., Germany, South Korea, and Israel. IC is characterized by leg cramps and pain while walking, caused by insufficient blood flow through arteries that are partially obstructed by atherosclerotic plaques.

“Completion of enrollment for our Phase II IC trial is a major milestone for Pluristem. We expect to report top line results in early 2018, which we intend to use to support our future application for a Biologics License Application (BLA) for approval to commercialize PLX-PAD for the treatment of critical limb ischemia (CLI), another peripheral artery disease. Now that we have completed the enrollment for this important study, Pluristem is ready to move full steam ahead with the enrollment of the recently announced Phase III trial in CLI. Our immediate goal is to bring PLX products to market as rapidly as possible,” stated Pluristem Chairman and CEO Zami Aberman.

“PLX-PAD cells are a potentially game-changing, non-invasive and much needed treatment for patients all over the world who suffer from peripheral artery disease. I am looking forward to the results of this IC trial, and to initiation of the Phase III in CLI (PACE study) this year,” commented Prof. Norbert Weiss, MD, Director of the Vascular Center at the Technical University of Dresden, Germany, principle investigator (PI) for the European part of the Phase II IC trial, and one of the PIs of Pluristem's upcoming Phase III trial in CLI.

“The option of treating peripheral artery diseases like IC and CLI through intramuscular injections of PLX-PAD cells is a promising one and a possible alternative to invasive procedures such as angioplasty or vascular surgery which may not be an option for a substantial portion of

patients. Pluristem's regenerative cell therapy may improve patient care and create economic benefits for the healthcare system," stated Dr. Manesh Patel, Chief of the Division of Cardiology at Duke University Health System, and the PI for the U.S. part of the Phase II IC trial.

Pluristem's IC trial is evaluating the safety and efficacy of PLX-PAD cells as compared to placebo. Both were administered via intramuscular injections in 172 patients with IC, Fontaine class IIb, Rutherford category 2-3. The primary efficacy endpoint is the change in maximal walking distance from baseline during an exercise treadmill test. Secondary endpoints include hemodynamic and quality of life measurements. Safety parameters are also being assessed.

About Intermittent Claudication

IC is a subset of peripheral artery disease, caused by atherosclerosis of the arteries in the lower extremities. 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 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 cell products 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 can be used 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 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 the expected timing of the reporting for top line results of the Phase II IC trial and patient recruitment for Pluristem's multinational Phase III PACE study in CLI, the potential for the safety data as a result of the Phase II IC trial to support Pluristem's Biologics License Application, when we discuss bringing PLX products to market as rapidly as possible, when we discuss the potential for PLX-PAD cells to treat IC and CLI and the potential impact such treatment could have in improving patient health care and creating economic benefits in the healthcare system. 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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