



## **Pluristem Advances its Multinational Phase III Critical Limb Ischemia Study, Targeting Initiation at 40 Active Sites by the End of 2017**

- *Austria's regulatory health agency clears CLI study and joins the U.S., U.K., and Germany in conducting the 250-patient Phase III trial*

**HAIFA, ISRAEL, July 10, 2017—** [Pluristem Therapeutics Inc.](#) (Nasdaq: PSTI, TASE: PSTI), a leading developer of placenta-based cell therapy products, announced today that Austria's regulatory health agency, the Austrian Agency for Health and Food Safety (AGES), has cleared Pluristem to begin enrollment in Austria for its pivotal Phase III trial of PLX-PAD cells to treat Critical Limb Ischemia (CLI). The trial is currently enrolling patients in the U.S., U.K., and Germany.

Pluristem's PLX-PAD cell therapy is one of a few therapies in the world to have been selected to take part in the European Medicines Agency's (EMA) Adaptive Pathways pilot project, which goal is to streamline development for promising innovative medicines to allow for early access in patients with serious conditions that lack adequate treatment. An interim efficacy analysis is planned to be conducted based on data from the first 125 patients. Positive results are expected to lead to early conditional marketing approval in Europe.

The Phase III CLI trial has received an \$8 million grant from the European Union's Horizon 2020 program, which will cover a significant portion of the costs of the multinational trial. Following the completion of the study, data from all 250 participants will be submitted to the EMA to apply for full marketing approval and will be reviewed by the U.S. FDA for a Biologics License Application (BLA) targeting commercialization.

“CLI is a severely debilitating and life-threatening disease that affects tens of millions of patients around the world. Approval for this trial and its innovative time-to-event endpoint by regulatory bodies worldwide reinforces our belief that our PLX-PAD cell therapy has great potential to successfully treat these patients and enable them to lead long and healthy lives,” said Zami Aberman, Chairman and Co-CEO of Pluristem. “The potential for early marketing approval is of key importance for us and we plan to continue our mission to utilize cell therapies to help combat devastating medical conditions.”

### **About the Study**

CLI is an advanced stage of peripheral artery disease, where fatty deposits block arteries in the legs, severely reducing blood flow and causing pain, non-healing ulcers, and gangrene.

Patients with CLI are at a high risk of amputation and death, and those unsuitable for revascularization are left with no adequate treatment options.

The Phase III trial will enroll a total of 250 patients across an estimated 40 clinical sites to evaluate PLX-PAD in the treatment of CLI in a double-blind, randomized, placebo-controlled trial. The patients will all have CLI Rutherford Category 5 – making them unsuitable candidates for revascularization. The patients will be injected twice intramuscularly (IM), two months apart, with 300 million cells or a placebo. The primary endpoint will be time to amputation or death, allowing for a survival analysis and increased data collection to reduce the number of patients required while still enabling statistically significant results for the trial.

### **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 different cell products each release their own 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. No tissue matching is required to administration of PLX cell products.

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 our pivotal Phase III trial of PLX-PAD cells, the expected interim efficacy analysis planned to be conducted based on data from the first 125 patients, our expectations that positive results from the Phase III CLI trial, if achieved, are expected to lead to early conditional marketing approval in Europe, the expected submission of study data from all 250 participants to the EMA in relation to the application for full marketing approval and a BLA to the FDA targeting commercialization, when we discuss the potential for PLX-PAD cells to treat CLI and when we discuss our plan to continue our mission to utilize cell therapies to help combat devastating medical conditions. 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.

**Contact:**

Karine Kleinhaus, MD, MPH  
Divisional VP, North America  
1-914-512-4109  
[karinek@pluristem.com](mailto:karinek@pluristem.com)

Efrat Kaduri  
Head of Investor & Public Relations  
972-74-710-8600  
[efratk@pluristem.com](mailto:efratk@pluristem.com)