



## **Pluristem in Key Discussions with Europe’s Adaptive Pathways Group on Phase II Protocol in Critical Limb Ischemia**

*Pluristem also presented plans to develop accelerated clinical programs for PLX cells in ischemic stroke, muscle wasting and hip fracture*

**HAIFA, ISRAEL, August 10, 2015** -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI) (TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that it has conducted detailed discussions with the European Adaptive Pathways Discussion Group regarding the clinical development plan for PLX cells in Critical Limb Ischemia (CLI) patients, and received guidance on the planned design of the initial Phase II trial of PLX cells in a subgroup of patients with severe CLI. Positive results from this trial could be sufficient for conditional approval to market PLX cells in this indication. Pluristem is receiving this in-depth guidance from European regulatory officials following the selection of this clinical program for the European Medicine Agency’s [Adaptive Pathways](#) project in May 2015.

In the discussions Pluristem also presented other indications for potential development through the Adaptive Pathways project; these were ischemic stroke, muscle wasting, hip fracture and additional subgroups of CLI.

The Adaptive Pathways project is part of the European Medicine Agency’s (EMA) efforts to improve timely access for patients to new therapies. It targets treatments with the potential to heal serious conditions with an unmet medical need, and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups.

“We are very pleased with the invaluable guidance we are receiving from EMA regulatory officials as we design our clinical trial protocol in a subgroup of CLI with particularly high unmet medical need,” stated Pluristem CEO Zami Aberman. “As we previously announced, we plan to apply to expand our program in CLI to include additional subgroups of the disease for development via the Adaptive Pathways, and expect to apply for consideration of other important indications with large potential markets. We are also benefiting from high-level guidance on these initiatives. Development of indications via the Pathways project could potentially provide patients earlier access to our therapies, while creating value to our shareholders by shortening time to market. In parallel, we continue to advance our clinical development programs for PLX cells in the U.S.”

## **About the Adaptive Pathways**

The purpose of Europe's Adaptive Pathways is to shorten the time it takes for innovative medicines to reach patients with serious conditions that lack adequate treatment options. The pathway is open to clinical programs in early stages of development only. After a therapy is selected for the program, the Adaptive Pathways Discussion Group provides detailed guidance to the applicant regarding the formal regulatory processes that precede a trial targeting early approval and further expansion of the indications.

## **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 cocktail 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, 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 that a successful phase II study could potentially be sufficient to receive early regulatory approval for marketing of PLX cells to treat CLI, when we discuss our plans to apply to expand our program in CLI to include additional subgroups of the disease, and in parallel to apply specifically to each of the other indications we presented to the EMA with large potential markets, or that this expansion allow us to optimize our long range planning for our [European?]clinical development side by side with our US clinical development plan and potentially cut time to market significantly or when we discuss that early regulatory approval after a successful Phase II trial could provide patients earlier access to our therapies, while creating value to our shareholders by shortening time to market. 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 surgical 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:**

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