

# Significant Progress for Pluristem: PLX Cells Were Selected for European Medicines Agency's Adaptive Pathways Pilot Project

Pluristem is targeting critical limb ischemia as the first indication for initial marketing authorization, potentially substantially shortening the time to market of PLX cells via the Adaptive Pathways

**HAIFA, ISRAEL, May 18, 2015** -- <u>Pluristem Therapeutics Inc</u>. (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced a significant advancement to its clinical development plan: the PLX cell program in critical limb ischemia has been selected for the European Medicines Agency's Adaptive Pathways pilot project. The goal of the project is to improve timely access for patients to new medicines. It allows for early marketing authorization of a therapy in a restricted patient population, followed by additional assessments and the possibility of later approval for use in broader patient populations. Critical limb ischemia (CLI), a severe blockage in the arteries of the legs which markedly reduces blood-flow, is associated with a significantly increased risk of leg amputation and death. It currently affects approximately one million people in the U.S., and the prevalence is expected to increase significantly in the coming decades. CLI therefore represents a major commercial opportunity. Acceptance of Pluristem's cells for the treatment of CLI into the Adaptive Pathways could significantly curtail the time and investment needed to bring this product to market.

"Acceptance into Europe's Adaptive Pathways pilot project is a tremendous milestone for Pluristem. It allows us to potentially commercialize our product earlier than expected," stated Pluristem CEO Zami Aberman. "We are extremely pleased with this outcome, which was one of the key elements we defined in our long term strategy to lead the cell therapy industry. Reducing time to market is a critical element of our strategy. The Adaptive Pathways has the potential to assist us in accomplishing this goal." Mr. Aberman added, "last week we announced a milestone in Japan, which is also an important territory for us. We are pursuing our strategy for expedited approval of PLX cells in Japan. We have applied to Japan's Accelerated Pathway for Regenerative Medicine for our PLX cells in critical limb ischemia, and Japan's Pharmaceuticals and Medical Devices Agency just validated the proposed quality and large-scale manufacturing methods for PLX-PAD cells for use in clinical trials."

Pluristem has already amassed experience in working with the European Medicines Agency and conducting trials in the EU. The Company completed both a Phase I trial in CLI and a Phase II trial in muscle injury in Europe. Pluristem is currently conducting a multinational Phase II trial in intermittent claudication, the less advanced stage of peripheral artery disease that can precede CLI,

and several of the trial sites are located in Europe. Pluristem has also effectively protected its IP in Europe. In October 2014 Pluristem successfully defended a European Patent whose claims cover treatment of ischemia with adherent placental cells which are propagated using a 3D culture. CLI is a type of ischemic disease, so the potential future treatment of CLI with PLX cells is protected by this robust European patent.

## About Critical Limb Ischemia and Its Market Potential

CLI is a chronic condition caused by a severe compromise of blood flow to the leg that is usually due to narrowing of the arteries as a result of the buildup of fatty deposits called plaque. Complications of this poor circulation can include gangrene and amputation of the affected limb. Estimates of the economic burden of CLI patients exceeds 10 billion dollars annually in the U.S. alone because of the high incidence of limb loss and need for major amputation. Current therapies have many limitations, especially in patients who cannot undergo angioplasty or surgery for revascularization. Anticipated increases in the incidence of CLI will likely generate an expanding market for innovative therapies such as PLX cells.

### 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 group conducts high level discussions and provides 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's patented PLX (PLacental eXpanded) cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cells are grown using the Company's proprietary three-dimensional expansion technology and are an "off-the-shelf" product that requires 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. For more information visit www.pluristem.com, the content of which is not part of this press release.

### 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, forward-looking statements are used in this press release when we discuss the potential of approving our cells for the treatment of CLI via the Adaptive Pathway to significantly curtail the time and investment needed to bring this product to market and potentially commercialize our

product earlier than expected, and to assist us with accomplishing our long term strategy to lead the cell therapy industry, or when we discuss pursuing our strategy for expedited approval of PLX cells in Japan. 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