



## **Pluristem's PLX Cells One Step Closer to Entering Japan's Accelerated Pathway for Regenerative Medicine**

***Pluristem completes successful meeting with PMDA and satisfies critical prerequisite for initiation of clinical study targeting fast-track approval in Japan***

**HAIFA, ISRAEL, May 13, 2015** -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapy products, today announced that Japan's Pharmaceuticals and Medical Devices Agency (PMDA) agreed with the proposed quality and large-scale manufacturing methods for PLX-PAD cells for use in clinical trials. This agreement is an important milestone for initiation of a Phase I/II study in critical limb ischemia through Japan's Accelerated Pathway for Regenerative Medicine. The new regulatory pathway could potentially significantly reduce time to market for cell therapies such as PLX cells.

“Pluristem is emerging as an early leader in the industry’s push to enter Japan’s newly established accelerated regulatory pathway. It is our hope that the PDMA will approve our application for a Phase I/II clinical study of PLX cells in critical limb ischemia via the Accelerated Pathway,” stated Pluristem CEO Zami Aberman.

Japan’s Accelerated Pathway for Regenerative Medicine went into effect in November 2014. According to the law, regenerative medicine therapies can receive conditional, time-limited approval for marketing, and be eligible for reimbursement, upon proof of safety and initial proof of efficacy. Safety and effectiveness need to be confirmed within 7 years after the conditional approval.

### **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](http://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 Japan's Accelerated Pathway for Regenerative Medicine to significantly reduce time to market cell therapies such as PLX cells, and when we discuss our hope that the PDMA will approve our application for a Phase I/II clinical study of PLX cells in critical limb ischemia via the Accelerated Pathway. 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.

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