



## **Pluristem Completes Large Scale Cell Therapy Formulation for Commercial and Clinical Trial Use**

*Scaled-up process enables the production potential of billions of live cells simultaneously*

HAIFA, Israel, November 7, 2012 Pluristem Therapeutics Inc. (NASDAQCM: [PSTI](#)) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today the Company has successfully completed the integration and testing of its new scaled-up formulation and manufacturing process to produce high-yield quantities of its Placental eXpanded (PLX) cells for clinical trials and potential commercial use. The increased automation and larger scale process allows the company to produce billions of live cells simultaneously.

As part of its manufacturing process, Pluristem has optimized growth conditions to maximize yields with lower costs. The company has minimized open manipulation steps in order to improve the aseptic quality and safety of the product. Critical steps have been automated including the process of harvesting and purification; the integration of closed system washing and concentration steps, and the product's final packaging has been changed to an aseptically automated vial system. In the past 15 months, Pluristem has invested resources and efforts to develop technologies resulting in an efficient, cutting edge production line. All of the integrated changes have been tested and will be integrated into Pluristem's new production site in Israel.

Pluristem recently announced it is in the final steps of building out its new manufacturing facility, which will have the capacity to produce commercial grade PLX cells. Once completed, and following regulators' approval, the new facility would have the capacity to produce PLX cells for the treatment of over 150,000 patients annually estimated by Pluristem at \$1 billion in production value.

"This new large scale manufacturing process allows us to run numerous clinical trials simultaneously around the globe, and also prepares us for potential commercial availability," stated Zami Aberman, Chairman and CEO of Pluristem. "Our progress with both our manufacturing process and facility are well on track."

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. ([PSTI](#)) (TASE:PLTR) is a leading developer of placenta-based cell therapies. The Company's patented PLX (PLacental eXpanded) cells are a drug delivery platform that releases a cocktail of therapeutic proteins in response to a host of local and systemic inflammatory and ischemic diseases. PLX cells are grown using the company's proprietary 3D micro-environmental technology and are an "off-the-shelf" product that requires no tissue matching prior to administration. Pluristem is focusing on the development of PLX cells administered locally to potentially treat systemic diseases and potentially obviating the need to use the intravenous route.

Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease when given locally. Additionally, Pluristem is developing PLX-PAD for cardiac ischemia; PLX-BMP for Acute Radiation Exposure, Bone Marrow Transplant Failure and Chemotherapy induced Bone Marrow Aplasia, PLX-ORTHO for orthopedic indications and PLX-PAH for Pulmonary Hypertension in collaboration with United Therapeutics. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

Pluristem has a strong patent and patent applications portfolio, 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) and follow Pluristem on Twitter [@Pluristem](#), the content of which is not part of this press release.

The Pluristem Therapeutics Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=6882>

### **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, when we discuss how the increased automation and larger scale process allows us to produce billions of live cells simultaneously, when we discuss the integration of changes into our new production site, when we discuss our new manufacturing facility, its planned capacity for production of PLX cells and estimated production value assuming the PLX cells product candidates are successfully developed and approved by the regulators, when we discuss that the new manufacturing process allows us to run numerous clinical trials simultaneously around the globe, and also prepares us for potential commercial availability, when we discuss that PLX cells are safe and can potentially treat PAD or that PLX cells are also potentially effective in other inflammatory/ischemic indications, we are using forward-looking statements. These forward-looking statements 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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