



## **US FDA Approves Pluristem's Commercial Scale Cell Manufacturing Process**

*Pluristem fortifies leadership position in cell therapy following multiple regulatory approvals of its new PLX cell mass production facility*

HAIFA, ISRAEL, March 06, 2014- Pluristem Therapeutics, Inc. (NasdaqCM: PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced that the United States Food and Drug Administration (FDA) has reviewed Pluristem's comparability studies of its PLacental eXpanded (PLX) cell products and granted approval for the Company to manufacture these products in its new commercial-scale cell manufacturing facility.

"We believe we have the largest, scalable, most efficient, most consistent and controlled process for manufacturing cell therapies," stated Zami Aberman, Chairman and CEO of Pluristem. "Knowing that the 'Process is the Product' in cell therapy, we have established our leadership position in the industry by focusing on our 3D commercial scale cell manufacturing processes. To be a successful company in the industry, we believe it is imperative to possess and control the manufacturing processes we have developed at Pluristem. We believe this FDA approval, combined with the approval given by the Paul-Ehrlich-Institute (PEI) of Germany announced on January 23, 2014, is an indication that these regulatory bodies see our proprietary 3D manufacturing process as a valid and sustainable commercial scale solution for potential cell therapies."

At its new state-of-the-art GMP manufacturing facility, Pluristem has implemented its proprietary, fully automated 3D cell expansion manufacturing platform that uses its patented high-throughput culturing technologies, 3D bioreactors, and downstream equipment. Pluristem's facility has the ability to efficiently produce approximately 150,000 doses of PLX cells annually, with batch-to-batch consistency, which potentially translates into significant economic value.

### **About Pluristem's 3D Manufacturing**

Pluristem's state-of-the-art GMP manufacturing site is located in MATAM industrial park, in Haifa, Israel and is equipped with 500 square meters of clean rooms in which PLX cells can be manufactured to support clinical trials and for commercial demand at time of regulatory approval. Pluristem develops and manufactures its products in full compliance with international quality standards, including US Food and Drug Administration (FDA), European Medicines Agencies (EMA), current Good Manufacturing Practices (cGMP) requirements and International Conference on Harmonization (ICH) quality guidelines. Pluristem believes that controlling the process is the key to success and invests significantly

in developing highly efficient, cutting-edge culturing systems for its PLX cell therapy products.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. 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 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, we are using forward-looking statements, when we discuss what it takes to be a successful company in our industry, or that regulatory bodies see our proprietary 3D manufacturing process as a valid and sustainable commercial scale solution for cell therapies, or when we discuss the capabilities of our new facility and how they potentially translate into significant economic value. 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)

Daya Lettvin  
Investor & Media Relations Director  
+972-54-674-5580  
[daya@pluristem.com](mailto:daya@pluristem.com)