



## **Pluristem Achieves Milestone Towards Completion of its New GMP Manufacturing Facility for Commercial Production of PLX Cells**

**HAIFA, ISRAEL**, October 23, 2012 – Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE:PLTR), a leading developer of placenta-based cell therapies, announced today a milestone in the build-out of its new clinical Good Manufacturing Process (cGMP) manufacturing facility for its Placental eXpanded (PLX) cells in MATAM Park, Haifa, Israel. Pluristem has initiated the Installation Qualification (IQ) validation process through Biopharmax Group Ltd., the company which is handling the build-out of Pluristem's facility. Following successful IQ, an Operation Qualification (OQ) will begin which marks the final stage of the build-out process prior to handing the facility over to Pluristem. The IQ/OQ validation includes systems such as the Heating, Ventilation, and Air Conditioning (HVAC), the Water for Injection (WFI), the Oil Free Air (OFA) and gas process systems.

Once constructed, the new facility will have the capacity to produce commercial grade PLX cells which will complement Pluristem's current manufacturing facility, with over 40,000 square feet. Once constructed, and assuming the PLX cells product candidates are successfully developed and approved by the regulators, 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.

Zami Aberman, Chairman and CEO of Pluristem commented, "We are extremely pleased with the progress of erecting one of the most technological advanced commercial grade cell manufacturing facility in the world."

Pluristem had first announced in July 2011 that it is expanding its manufacturing facility as part of Pluristem's strategy to develop its "top-of-the-line" intellectual property and manufacture its cell therapy product candidates in July 2011. Pluristem's new regenerative medicine facility is designed specifically to meet both FDA and EMA regulatory requirements, as well as the standards outlined by the Israeli Ministry of Health. For more information, please visit: [http://www.pluristem.com/index.php?option=com\\_content&view=article&id=176:-april-6&catid=4&Itemid=104](http://www.pluristem.com/index.php?option=com_content&view=article&id=176:-april-6&catid=4&Itemid=104)

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. (NASDAQCM: 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](https://twitter.com/Pluristem), 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, when we discuss our new manufacturing facility, its construction, its validation process, 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, 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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