

# Pluristem's Manufacturing Facility Approved by European Auditors for Phase III Trials

## Company can expand into, and advance its clinical trials, in any European Union member nation

HAIFA, ISRAEL, April 28, 2014 -- Pluristem Therapeutics Inc. (NasdaqCM:PSTI; TASE: PLTR) today announced that its new manufacturing facility has received the European Union's Qualified Person Declaration. With this declaration, Pluristem is now approved to use cell therapies manufactured at its state-of-the-art facility located in Haifa, Israel, in all phases of its clinical trials conducted in the European Union, including Phase I, Phase II and Phase III.

The Qualified Person inspection was conducted in line with the European Union's Good Manufacturing Practice (GMP) legislation, directives and guidelines. The audit focused on the design, construction and validation of Pluristem's new facility, equipment, utilities, and quality management systems. Pluristem's manufacturing and cell expansion operations were deemed compliant with EU GMP requirements.

"This Qualified Person declaration enables us to expand our clinical site locations into any European Union member nation through each phase of our trials," stated Zami Aberman, Chairman and CEO of Pluristem. "We believe Pluristem's advanced, commercial scale cell manufacturing facility is one of our Company's key strategic assets and gives us significant competitive advantage in the industry as we move our clinical development pipeline forward."

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 U.S. 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. Pluristem's manufacturing facility and its commercial scale manufacturing process have received approval from the <u>U.S. Food and Drug Administration</u> and the <u>Paul-Ehrlich-Institute (PEI)</u>, Germany's health authority.

### **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, 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 expanding our clinical trials into any European Union nation member, or that our facility gives us significant competitive advantage in the industry as we move our clinical development pipeline forward. These forwardlooking 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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