



Israel's Ministry of Health Approves Pluristem's Commercial-Scale 3D Cell Manufacturing Process Used at Its New Haifa Facility;

This follows clearances from U.S., E.U., German, and South Korean regulators

HAIFA, ISRAEL, July 31, 2014 -- [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI, TASE: PLTR), a leading developer of placenta-based cell therapies, announced today that it has completed the approval process and received final clearance from a fifth regulatory agency for its 3D cell therapy manufacturing processes in use at its new facility in Haifa. The latest approval comes from Israel's Ministry of Health and follows similar clearances from the [U.S.](#) Food and Drug Administration, the [European Union's](#) Qualified Person, [Germany's](#) Paul Ehrlich Institute, and the [South Korean](#) Ministry of Food and Drug Safety.

"This latest regulatory clearance further validates our proprietary cell manufacturing processes, which we believe are state-of-the-art and unmatched in the cell therapy arena. Our Haifa facility has the capacity to produce approximately 150,000 doses of PLX cells annually, with batch-to-batch consistency, which potentially translates into significant economic value" stated Pluristem CEO Zami Aberman. "This latest approval also exemplifies our strategy of working with multiple regulatory bodies in order to establish Pluristem as a leading developer of cell therapies and to set the standards for this area of manufacturing," added Aberman.

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 in sufficient quantities to support late-phase clinical trials and commercial demand at time of regulatory approval. Pluristem manufactures its products in full compliance with the U.S. Food and Drug Administration (FDA) and European Medicines Agencies (EMA) current Good Manufacturing Practices (cGMP). Pluristem believes that control of the production process is critical for the successful manufacture of cell therapies and invests significantly in developing highly efficient, cutting-edge culturing systems for its range of PLX cell 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 protein delivery platform that releases a cocktail of therapeutic proteins in response to inflammation or ischemia. 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 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.

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