



Pluristem Therapeutics Set To Enter Bone Marrow Disease Market As it is Preparing to Apply for Orphan Drug Status with the FDA for the treatment of Aplastic Bone Marrow

HAIFA, Israel, July 23, 2012 -- [Pluristem Therapeutics, Inc. \(PSTI\)](#) (TASE:PLTR), a leading developer of placenta-based cell therapies, today announced it is preparing to apply to the U.S. Food and Drug Administration for approval of its PLacental eXpanded (PLX) cells for the treatment of aplastic bone marrow as an Orphan Drug. Gaining Orphan Drug status approval is part of Pluristem's strategy for penetrating the bone marrow recovery market, starting with treatment of aplastic anemia, a disease in which bone marrow greatly decreases or stops production of blood cells and which strikes five to ten people in every million.

Gaining Orphan Drug Status carries multiple potential benefits, including the possibility of an expedited regulatory process, availability of grant money, certain tax credits and seven years of market exclusivity. In August 2011, Pluristem successfully applied for, and received, Orphan Drug Status from the FDA for its PLX cell therapy in the treatment of Buerger's disease.

Pluristem announced earlier this year that its PLX cells had saved the life of a seven year-old girl suffering from aplastic bone marrow and who had undergone two failed bone marrow transplants. With her condition rapidly deteriorating, her doctors injected Pluristem's PLX cells intramuscularly, following which the girl experienced a reversal of her condition with a significant increase in her red blood cells, white blood cells and platelets.

"With her body rejecting all possible treatment -- and with no other options -- we finally turned to Pluristem's PLX cells, which literally saved her life," said Professor Reuven Or, Director of Bone Marrow Transplantation, Cell Therapy and Transplantation Research Center at Hadassah Medical Center, and the child's primary physician. "The results of this unique case indicate that PLX cells may be effective in treating other diseases that affect the bone marrow." added Professor Or.

"We are very encouraged by the therapeutic results we've seen for our PLX cells in the treatment of aplastic anemia and we intend to pursue every avenue to bring it to market for this indication as swiftly as possible and to extend the indication to other clinical situations involving bone marrow deficiencies," said Zami Aberman, Chairman and CEO of Pluristem. "As with the case of the young girl we successfully treated, PLX cells may potentially save lives when no other alternative is working. Orphan Drug Status in the U.S. would help accelerate our path to full FDA approval and we intend to apply for a similar designation in Europe and global territories."

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 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, the content of which is not part of this press release. Follow Pluristem on Twitter [@Pluristem](#).

[CLICK HERE](#) to watch a video where CLI patients and doctors involved with the clinical trials share their stories, 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 our plans to enter into the aplastic bone marrow market, when we discuss our plans to apply to the U.S. FDA for Orphan Drug Status for our PLacental

eXpanded (PLX) cells in the treatment of aplastic bone marrow and for a similar designation in Europe and global territories, the impact of such status, how we will bring this treatment to the market and how this treatment may potentially save lives when no other alternative is working, when we discuss how our PLX cells had literally saved the life of a girl who had undergone several bone marrow transplants that had failed and how the results of this case indicate that PLX cells may be effective in treating other diseases that affect the bone marrow, when we discuss that Data from two phase I studies indicate that our PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease, or when we discuss how pre-clinical animal models have demonstrated 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 our clinical trials; 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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