



Pluristem Receives FDA Orphan Drug Status Designation for Treatment of Aplastic Anemia

HAIFA, Israel February 21, 2013 -- [Pluristem Therapeutics Inc.](#) (NASDAQCM: PSTI) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that the U.S. Food and Drug Administration (FDA) has designated Pluristem's PLacental eXpanded (PLX) cells orphan drug status for the treatment of aplastic anemia.

Orphan drug designation qualifies a company for several benefits under the Orphan Drug Act of 1983 (ODA), as amended. These benefits include a 7-year period of orphan drug exclusivity upon product approval, a tax credit for certain clinical testing expenses for the orphan drug, written guidance on the non-clinical and clinical studies needed to obtain marketing approval of an orphan drug, and orphan drug grants.

This is Pluristem's second orphan drug designation from the FDA. The company also received orphan drug status from the FDA for its PLX cells for the treatment of Buerger's disease in August of 2011.

Aplastic anemia is a rare but serious disorder with a prevalence of less than 200,000 in the U.S. The disease is caused by the failure of hematopoietic stem cells (HSCs) contained within the bone marrow to produce red blood cells, white blood cells and platelets. The disease is considered an emergency and patients are supported with blood products in anticipation of a bone marrow transplant (BMT) or drugs that suppress the immune system.

"Receiving orphan drug designation for aplastic anemia is an important event for Pluristem as it opens pathways for using our PLX cells for additional indications in the field of hematology," stated Zami Aberman, Chairman and CEO of Pluristem.

Pluristem has established a clinical advisory board made up of key opinion leaders in the area of bone marrow transplantation from the United States, Europe and Israel to provide the company with valuable insight towards expanding its activities in the treatment of the bone marrow diseases and transplantations.

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 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, 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 that this indication may open pathways for the use of PLX cells in additional indications in the field of hematology, or when we discuss the expansion of our activities in the treatment of the bone marrow diseases and transplantations. 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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