



Pluristem Reports Status of Orphan Drug Application for Aplastic Anemia

FDA acknowledges aplastic anemia as rare disease and requests further data from the company in connection with application

HAIFA, ISRAEL, November 21, 2012 -- Pluristem Therapeutics, Inc. (NASDAQCM:PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced that the U.S. Food and Drug Administration (FDA) has updated the Company on its application to designate Pluristem's PLacental eXpanded (PLX) cells orphan drug status in the treatment of aplastic anemia. The FDA acknowledged that aplastic anemia is a rare disease with prevalence in the United States of less than 200,000. This serves as confirmation that aplastic anemia is an indication for which candidate treatments are eligible for orphan drug status. The FDA has also requested that Pluristem provide additional information and data for further analysis before the FDA can determine if the PLX cells can qualify for orphan drug designation for aplastic anemia.

"We look forward to providing the additional information that the FDA needs in connection with our orphan drug status application for Aplastic Anemia. We appreciate the very productive working relationship we have with the FDA, as we present PLX cells as candidates for the treatment of a range of therapeutic indications," stated Zami Aberman, Chairman and CEO of Pluristem.

About Orphan Drug Status

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.

About Pluristem Therapeutics Inc.

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 use of PLX cells administered locally to treat systemic diseases and potentially obviating the need to use the intravenous route.

Pluristem has a strong patent portfolio, GMP certified manufacturing and research facilities as well as strategic relationships with major research institutions.

For more information visit www.pluristem.com, the content of which is not part of this press release.

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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 say that we look forward to providing the additional information that the FDA needs, or when we discuss presenting our PLX cells as candidates for treatment of a range of therapeutic indications. 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; 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.