Pluristem Submits FDA Orphan Drug Application for Preeclampsia

Orphan Drug Designation may provide benefits including 7 year market exclusivity, tax credits, and FDA's guidance on clinical studies

HAIFA, ISRAEL, February 20, 2014- Pluristem Therapeutics, Inc. (NasdaqCM: PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced it is submitting its application to the United Stated Food and Drug Administration requesting the Company to be granted Orphan Drug Designation for its PLacental eXpanded (PLX-PAD) cells in the treatment of severe preeclampsia.

Orphan Drug Designation may qualify a company for several benefits under the Orphan Drug Act of 1983 (ODA), as amended. These benefits may 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.

"Having just recently established our Preeclampsia Steering Committee comprised of key medical opinion leaders, this Orphan Drug application submission is an important step in advancing our preeclampsia development program," stated Pluristem Chairman and CEO Zami Aberman. "The tremendous unmet medical need makes this indication one of our top priorities. We look forward to advancing into human trials and we are hopeful that the very strong preclinical data for PLX cells will translate into similar results at the clinical level."

Pluristem has successfully received Orphan Drug Designation from the FDA for its PLX cells in two other indications: the treatment of aplastic anemia; and the treatment of Buerger's disease.

About Preeclampsia

Preeclampsia is one of the most common medical complications of pregnancy, and one of the leading known causes of premature births, stillbirths and early neonatal and maternal deaths. If left untreated it can progress to eclampsia, the life-threatening occurrence of seizures during pregnancy. The only definitive treatment for preeclampsia is abortion or delivery. The disease occurs after the 20th week of pregnancy, and is characterized by high blood pressure and significant amounts of protein in the urine or end-organ dysfunction. According to the World Health Organization, preeclampsia occurs in approximately 6%–8% of pregnancies worldwide. It is estimated that preeclampsia costs the global health care system $3 billion annually.

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 the orphan drug submission and receipt of orphan drug status, the potential of receipt certain benefits in case we receive orphan drug status, and our statements regarding the status of the human trials we are conducting and potential success thereof, or when we discuss advancing our cell therapies to serve unmet medical needs, or that we are ready and set to meet the significant opportunities ahead. 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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