U.S. Food & Drug Administration Grants Orphan Drug Designation to Pluristem's PLX-PAD Cells for Treatment of Severe Preeclampsia

PLX cells were demonstrated to be safe for both the mother and fetus and improved several parameters of preeclampsia in several animal studies

HAIFA, ISRAEL, December 31, 2015 -- Pluristem Therapeutics Inc. (NasdaqCM, TASE: PSTI), a leading developer of placenta-based cell therapy products, today announced that the U.S. Food and Drug Administration has granted the Company's PLX-PAD cells Orphan Drug Designation in the treatment of severe preeclampsia. Preeclampsia is among the most common medical complications of pregnancy and a leading cause of premature births, stillbirths and neonatal and maternal deaths. There is no cure except delivery. Due to high risks to the mother, women diagnosed with severe preeclampsia are usually delivered promptly, even if the baby will be born prematurely and may suffer permanent disabilities as a result. Severe preeclampsia occurs in approximately 1% of pregnancies in Western countries.

Benefits of Orphan Drug Designation for PLX-PAD cells include close guidance that may accelerate time to marketing approval, orphan drug grants, tax credits, and a 7-year market exclusivity upon marketing approval. It is estimated by different sources that preeclampsia costs the global health care system about $3 billion annually.

"Attainment of Orphan Drug Designation for our cells in severe preeclampsia exemplifies our global strategy of bringing cell therapies to patients through accelerated approval pathways," stated Pluristem Chairman and CEO Zami Aberman. "We are encouraged by the US FDA designation that demonstrates Pluristem's commitment to the program and the potential promise it holds to address a serious, unmet medical need faced by pregnant women every year"

PLX-PAD cells improved several parameters of preeclampsia in animal models in a study conducted in collaboration with Brett Mitchel PhD, Associate Professor of Internal Medicine at the Cardiovascular Research Institute (CVRI) of the Texas A&M College of Medicine. In a different animal study conducted a Charles River Laboratories, PLX-PAD cells were demonstrated to be safe for both the mother and fetus. As previously requested by the FDA, study in additional animal model (over expression of sFLT-1) to confirm the efficacy of PLX-PAD is on-going to test the efficacy of PLX-PAD in an additional therapeutic pathway. Data is expected in H1 of 2016.

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. 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. The disease may lead to liver and renal failure, central nervous system (CNS) abnormalities including seizures, and disseminated intravascular coagulopathy. The only definitive treatment for preeclampsia is delivery. Severe preeclampsia, which occurs in 1% of pregnancies in the U.S., is defined by the presence of at least one additional symptom in a patient meeting the criteria for preeclampsia; these additional symptoms include severe high blood pressure, signs of severe kidney malfunction, low platelets, persistent headaches, and pulmonary edema.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX (PLacental eXpanded) cells. The cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cell products are grown using the Company's proprietary three-dimensional expansion technology. They are off-the-shelf, requiring 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.

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 benefits of Orphan Drug Designation for PLX cells, or when we discuss our global strategy of bringing cell therapies to patients through accelerated approval pathways, or when we discuss our commitment to the severe preeclampsia program and the potential promise it holds to address a serious, unmet medical need faced by pregnant women every year. 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 clinical 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. 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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