

# Preclinical Research Shows PLX Cells May Be Effective in Treating Preeclampsia

## No treatment exists today for the most common medical complication of pregnancy

HAIFA, Israel May 13, 2013 -- Pluristem Therapeutics Inc. (NASDAQCM: PSTI) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today its PLacental eXpanded (PLX) cells tested in preclinical animal models of preeclampsia effectively improved several parameters of the disease. The study was 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. Dr. Mitchel will present details of the study on May 30<sup>th</sup> at the Society for Gynecological Investigation Summit in Jerusalem.

Preeclampsia is the most common medical complication of pregnancy and a leading cause of premature births, stillbirths and early neonatal and maternal deaths. If left untreated, it can develop into eclampsia, the life-threatening occurrence of seizures during pregnancy. The only known treatment for eclampsia or preeclampsia is abortion or delivery. The disease occurs in previously healthy women after their 20<sup>th</sup> week of pregnancy and symptoms include high blood pressure and significant amounts of protein in the urine. 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. May was recognized as National Preeclampsia Awareness Month by U.S. Congresswomen in an effort to improve outcomes for women and babies.

Since preeclampsia is a human pregnancy specific disease, defined as the occurrence of hypertension and significant proteinuria, Dr. Mitchell has established and published two preeclampsia rodent models that exhibits the fundamental features of preeclampsia; pregnancy dependent hypertension and proteinuria. PLX cells administered IM were tested against cell-free medium in these two preeclampsia animal models. Pregnant mice that developed gestational hypertension and proteinuria and received PLX cells demonstrated several positive physiologic, immunologic and histologic findings indicating that PLX cells could be effective in treating preeclampsia.

These findings included:

- A progressive, significant (p<0.05) reduction of systolic blood pressure to the level of normal pregnant mice within 3 days of PLX cell administration. Additionally, PLX cells had no effect on blood pressure when given to normal pregnant mice.
- Significant (p<0.05) reduction of urinary protein excretion to levels seen in normal pregnant mice within 4 days after PLX cell administration. Additionally, PLX cells had no effect on urinary protein excretion when given to normal pregnant mice.
- Significant (p<0.05) increase in endothelial function (as measured by acetylcholine-induced relaxation) to levels seen in normal pregnant mice within 4 days following PLX cell administration.
- Significant (p<0.05) reduction in the weight of the spleen to levels seen in normal pregnant mice within 4 days following PLX cell administration. Additionally, PLX cells did not increase the spleen size in pregnant mice demonstrating the lack of immunogenicity of these cells.
- No significant differences in the number of pups per litter or fetal demise per litter was observed for all groups suggesting PLX cells do not harm the fetus.

Dr. Mitchell stated, "We were pleasantly surprised that a one-time treatment with PLX cells during pregnancy was able to safely and effectively normalize blood pressure and kidney function in mice with experimental preeclampsia. Our preliminary results suggest that the factors secreted by these cells were able to restore endothelial function while having no deleterious effects on the mother or the fetuses. Since there are currently no treatments for preeclampsia, we are hopeful that women with PE will soon benefit from this promising cell therapy."

Zami Aberman, Chairman and CEO stated, "While specific mechanisms remain to be determined, this preliminary data demonstrating that Pluristem's PLX cells are a potential novel therapeutic for the treatment of preeclampsia is very exciting. We look forward to continuing our research with a goal to enter the clinic as soon as possible for this common, potentially lethal disease that currently has no acceptable treatment."

### **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, when we discuss how our PLX cells are a potential novel therapeutic for the treatment of preeclampsia, or that we look forward to continuing our research with a goal to enter the clinic as soon as possible for preeclampsia, we are using forward-looking statements. These forwardlooking 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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