



Pluristem's PLX Cells Demonstrate Efficacy in Preclinical Study for Graft versus Host Disease

Both intramuscular and intravenous administrations show statistically significant improvement

Clinical Path Being Investigated with Leading Medical Institutions

HAIFA, Israel October 01, 2013 -- [Pluristem Therapeutics Inc.](#) (NASDAQCM: PSTI) (TASE:PLTR), a leading developer of placenta-based cell therapies, announced today that the company's PLacental eXpanded (PLX) cells demonstrated efficacy in a preliminary animal experiment for the treatment of Graft versus Host Disease (GvHD) following bone marrow transplantation (BMT). The results showed that PLX cells, regardless of their administration route, intravenous (IV) or intramuscular (IM), demonstrated a statistically significant improvement ($p < 0.05$) in the GvHD score. Following interest from leading medical institutions, Pluristem is investigating a potential cooperation to bring this indication to a clinical trial.

GvHD may occur after BMT when patients receive bone marrow tissue or cells from a donor and these newly transplanted cells regard the recipient's body as foreign, attacking the recipient's body. The [global incidence](#) of acute GvHD ranges from 26% to 34% in recipients of fully matched sibling donor grafts, to 42% to 52% in recipients of matched unrelated donor grafts.

The animal study was conducted in the laboratories of the Department of Bone Marrow Transplantation, Hadassah Medical Center, the Hebrew University, Jerusalem.

In the study, mice underwent total body irradiation and after twenty-four hours received a semi-allogeneic BMT. PLX cells, or the same volumes of the control vehicle, were then injected IV or IM into the mice concurrently with the BMT (day 0, ~20h after irradiation) and 5 days post-irradiation. PLX markedly reduced the GvHD score, comprised of weight loss, diarrhea, skin and fur integrity and survival. This significant ($p < 0.05$) reduction in the GvHD score occurred in both the IV and IM treatment groups 42 days after transplantation. Moreover, histological examination of the liver revealed reduced hepatic lymphocyte infiltration, a marker for the severity of GvHD occurring in the PLX-treated groups without preference to the route of administration.

“Based on the results of this pre clinical study suggesting our PLX cells may be effective in GvHD, we are pleased with the interest of leading medical institutions to use our PLX cells and will consider a cooperation to advance into a clinical program for this indication,” said Zami Aberman, Chairman and CEO of Pluristem. “This indication would be complementary to the other indications we plan to pursue in the hematology field. Additionally, this study also gives Pluristem another data point demonstrating PLX cells do not have to be given intravenously to obtain a systemic effect.”

IM Administration with Systemic Effect

This preclinical study marks the second time that the IM administration of PLX cells has demonstrated a systemic effect with efficacy in a hematological disease and the fourth time when preclinical animal models for other indications are included. Pluristem previously reported that the IM injection of PLX cells demonstrated a systemic effect in preclinical studies of [Peripheral Artery Disease](#) (PAD), [Preeclampsia](#) and [Acute Radiation Sickness](#) (ARS). Additionally, systemic, beneficial effects were also noted in three patients given PLX cells IM compassionately for [Bone Marrow Failure](#).

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 that the results of this pre clinical study suggest our PLX cells may be effective in GvHD, or that we will consider a cooperation to advance into a clinical program for GvHD, or that we plan to pursue other indications in the hematology field, we are using forward-looking statements. 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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