



Pluristem Receives Approval to Commence a Phase I/II Study for Muscle Regeneration in Germany

Clinical trial to demonstrate safety and efficacy of PLX cells for regeneration of injured gluteal muscle following total hip replacement

HAIFA, ISRAEL, August 7, 2012 -- [Pluristem Therapeutics, Inc.](#) (NASDAQCM:PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced it has received approval from the Paul-Ehrlich-Institute (PEI), the medical regulatory body in Germany, to commence a Phase I/II randomized, double blind, placebo controlled study to assess the safety and efficacy of its PLX cells, through intramuscular injections, for the regeneration of injured gluteal musculature following total hip replacement.

Muscle damage is a common result of hip replacement surgery, which is rising in incidence in Europe and other developed nations. The incidence of hip replacement surgery in the European Union is approximately 150 per every 100,000 people. On average, the number of hip replacement surgeries in the EU increased one-third between 1998 and 2008. The company believes that in the United States there are 300,000 total and partial hip replacements each year.

18 patients scheduled to undergo a total hip replacement will participate in this study. The subjects will randomize to one of three treatment arms, including two active-treatment arms and one placebo arm. On day one of the study, subjects will undergo total hip replacement surgery. Subjects will receive either PLX cells or placebo, through intramuscular injection, during the procedure. The expected total active duration of the study for each subject is 12 months.

"This is an important new indication for PLX cells, as beyond potentially showing safety and efficacy in muscle regeneration after hip replacement surgery, this opens PLX cells to the possibility of addressing large new markets in sports injury treatment and muscular regenerative medicine," said Zami Aberman, Chairman and CEO of Pluristem. "We are very pleased with the growing number of new indications and new clinical trials currently initiated for our PLX cells around the world."

About Pluristem Therapeutics

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

Data from two phase I studies indicate that Pluristem's first PLX product candidate, PLX-PAD, is safe and potentially effective for the treatment of end stage peripheral artery disease when given locally. Additionally, Pluristem is developing PLX-PAD for cardiac ischemia, PLX-RAD for Acute Radiation Exposure, Bone Marrow Transplant Failure and Chemotherapy induced Bone Marrow Aplasia, PLX-ORTHO for orthopedic indications and PLX-PAH for Pulmonary Hypertension in collaboration with United Therapeutics. Pluristem's pre-clinical animal models have demonstrated PLX cells are also potentially effective in other inflammatory/ischemic indications, including diastolic heart failure, inflammatory bowel disease, neuropathic pain and pulmonary fibrosis.

Pluristem has a strong patent portfolio, 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, Follow Pluristem on Twitter [@Pluristem](https://twitter.com/Pluristem), 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 say that our PLX cells may be safe and effective in treating muscle regeneration after hip replacement surgery, that treatment with PLX cells may address large new markets in sports injury treatment and muscular regenerative medicine, when we refer to a growing number of new indications and new clinical trials currently initiated for our PLX cells, that data from two phase I studies in Critical Limb Ischemia indicates that PLX-PAD is safe and potentially effective and when we discuss other indications that may be treated with our PLX cells, we are using forward-looking statements. 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; 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.

Contact:

Pluristem Therapeutics Inc.:

William Prather R.Ph., M.D. Sr. VP Corporate Development
1-303-883-4954

William.PratherMD@pluristem.com

Daya Lettvin

Investor & Media Relations Director

+972-54-674-5580

daya@pluristem.com

Media Contact:

Matthew Krieger

Finn Partners – for Pluristem

+972-54-467-6950

matthew@finnpartners.co.il