



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.