Pluristem's Phase I/II Muscle Injury Trial Successfully Meets Primary Safety & Efficacy Endpoints

PLX-PAD cells show statistically significant improvement over placebo in the change of the maximal contraction force of the gluteal muscle

HAIFA, ISRAEL, January 21, 2014 **-** Pluristem Therapeutics Inc. (NasdaqCM: PSTI; TASE: PLTR), a leading developer of placenta-based cell therapies, today announced top-line results from its Phase I/II clinical trial testing the safety and efficacy of PLacental eXpanded (PLX-PAD) cells in the treatment of muscle injury. The trial indicated PLX-PAD cells were safe and statistical significance was reached (p=0.0067) for the primary efficacy endpoint of the study, the change in maximal voluntary isometric contraction force of the gluteal muscle at six months after total hip replacement . Patients treated with PLX-PAD had a greater improved change of maximal voluntary muscle contraction force than the placebo group. These results provide evidence that PLX cells may be efficacious in the treatment of orthopedic injuries including muscles and tendons.

This Phase I/II trial was a randomized, placebo-controlled, double-blinded study conducted at the Orthopedic Clinic of the Charité University Medical School under the auspices of the Paul-Ehrlich-Institute (PEI), Germany's health authority. The injured muscle studied was the gluteus medius muscle in the buttock. Total hip replacement surgery via the standard transgluteal approach necessitates injury of the gluteus medius muscle, and post-operative healing is crucial for joint stability and function.

The 20 patients in the study were randomized into three treatment groups. Each patient received an injection in the gluteal muscle that had been traumatized during surgery. One group was treated with 150 million PLX-PAD cells per dose (n=7), the second was administered 300 million PLX-PAD cells per dose (n=6), and the third received placebo (n=7).

The primary safety endpoint was clearly met, with no serious adverse events reported at either dose level. The study showed that PLX-PAD cells were safe and well tolerated.

The primary efficacy endpoint of the study was the change in maximal voluntary isometric contraction force of the gluteal muscle at six months post-surgery. Efficacy was shown in both PLX-PAD treated patient groups, with the group receiving the 150 million cell dose displaying a statistically significant 500% improvement over the placebo group in the change of the maximal contraction force of the gluteal muscle (p=0.0067). Patients treated at the 300 million cell dose showed a 300% improvement over the placebo (p=0.18).

An analysis of the macrostructure of the gluteal muscle using magnetic resonance imaging (MRI) indicated an increase in muscle volume in those patients treated with PLX-PAD cells versus the placebo group. This efficacy endpoint was demonstrated in both PLX-PAD treated patient groups, with the group receiving the 150 million cell dose displaying a statistically significant superiority over the placebo group. Patients treated at the 150 million cell dose showed an approximate 300% improvement over the placebo in the analysis of muscle volume (p=0.004). Patients treated at the 300 million cell dose showed an approximate 150% improvement over the placebo in the change of muscle volume (p=0.19). The complete dataset that includes biopsy results and functional assessments will be presented at a medical conference once the final analyses are completed.

The study's Senior Scientist, Dr. Tobias Winkler of the Center for Musculoskeletal Surgery, Julius Wolff Institute Berlin, Charité – Universitaetsmedizin Berlin, Germany, commented, "I am very impressed with the magnitude of the efficacy results seen in this trial. PLX cells demonstrated safety and suggested that the increase in muscle volume could be a mechanism for the improvement of contraction force."

Zami Aberman Chairman and CEO stated, "This was a very important study not only for Pluristem but for the cell therapy industry in general. The study confirms our pre-clinical findings that PLX-PAD cell therapy can be effective in treating muscle injury. Having a statistically significant result for our primary efficacy endpoint is very encouraging and consistent with our understanding of the mechanism of action associated with cell therapy. Based on these results, we intend to move forward with implementing our strategy towards using PLX cells in orthopedic indications and muscle trauma."

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 the results of our clinical trial and that PLX cells may be efficacious in the treatment of orthopedic injuries including muscles and tendons, or our intention to move forward with implementing our strategy towards using PLX cells in orthopedic indications and muscle trauma, 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. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions or that historic results referred to in this press release would be interpreted differently in light of additional research and clinical and preclinical trials results. 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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