



## **Pluristem Announces Significant New Finding from its Phase I/II Muscle Injury Trial and Excellent Safety Profile for PLX-PAD Cells at Twelve Months**

HAIFA, ISRAEL, Feb 2, 2015 – [Pluristem Therapeutics Inc.](#) (NasdaqCM: PSTI; TASE: PSTI), a leading developer of placenta-based cell therapies, announced an important new finding from its Phase I/II clinical trial of PLacental eXpanded (PLX-PAD) cells in the treatment of muscle injury after total hip arthroplasty (THA). Data showed that six months after surgery the magnitude of improvement in muscle force of the contralateral (non-operated) gluteal muscle was approximately 40 times larger in patients treated with 150 million PLX-PAD cells than in those who received placebo, and the difference was statistically significant (19.4 vs 0.5 Nm,  $p=0.0114$ ). Patients treated with 300 million PLX-PAD cells also showed a larger increase in muscle force than patients injected with placebo (9.48 vs 0.46 Nm,  $p=0.227$ ). Pluristem further announced positive twelve-month safety data from the trial. These findings follow the January 21, 2014 [announcement](#) that the study had met its primary efficacy and safety endpoints. The primary efficacy finding was the change in maximal voluntary isometric contraction force of the gluteal muscle in the operated leg at six months after total hip replacement. There was a large and statistically significant improvement in patients who were injected with 150 million cells versus those who received placebo (31.1 vs 5.4 Nm,  $p=0.0067$ ).

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 impressed with the magnitude of the effect seen in the treated and contralateral legs. PLX cells demonstrated good safety and these newest findings suggest that intramuscular injection of PLX cells might potentially improve overall muscle functionality."

Zami Aberman, Chairman and CEO, stated "It is very encouraging to have a large and statistically significant effect of PLX-PAD cells on our primary efficacy endpoint and also the unexpected finding of increased muscle strength in the non-operated leg. Although additional confirmatory studies are needed, these findings support our previous studies in which we showed that injection of PLX-PAD cells into muscle generates a systemic effect. The findings also open up new possibilities for the potential use of PLX-PAD cells. Based on these results, we intend to continue to develop PLX-PAD in

orthopedic indications including sports injuries and muscle trauma, as well as muscle wasting and rehabilitation.”

The Phase I/II trial was a randomized, double blind, placebo controlled study conducted at the Orthopedic Clinic of the Charité Universitätsmedizin Berlin jointly with the Berlin-Brandenburg Center for Regenerative Therapies under the auspices of the Paul-Ehrlich-Institute (PEI), Germany's health authority. The injured muscle studied was the gluteus medius muscle, which is intentionally cut during total hip arthroplasty using the transgluteal approach. 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 injections in the gluteal muscle that had been traumatized during surgery. One group was treated with 150 million PLX-PAD cells (n=7), the second was administered 300 million PLX-PAD cells (n=6), and the third received placebo (n=7). The primary efficacy endpoint was clearly met and the safety profile at 12 months was excellent.

### **About Pluristem Therapeutics**

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company's patented PLX (PLacental eXpanded) cells release a cocktail of therapeutic proteins in response to inflammation, ischemia, hematological disorders, and radiation damage. PLX cells are grown using the Company's proprietary three-dimensional expansion 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](http://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, forward-looking statements are used in this press release when we discuss the follow up results of our muscle injury clinical trial and the potential of PLX cells to improve overall muscle functionality, when we discuss how the new findings open new possibilities for the potential use of PLX-PAD cells and our intention to continue to develop PLX-PAD in orthopedic indications. 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.

Contact:

Pluristem Therapeutics Inc.  
Karine Kleinhaus, MD, MPH  
Divisional VP, North America  
1-914-512-4109  
[karinek@pluristem.com](mailto:karinek@pluristem.com)