



U.S. FDA Clears Pluristem's Phase III Study in Treatment of Muscle Injury Following Hip Fracture Surgery

Multinational study expected to include clinical sites in U.S. Israel and Europe, where study has been awarded an \$8.7 million grant from European Horizon 2020 Program

HAIFA, Israel, April 25, 2018 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI), a leading developer of placenta-based cell therapy products, announced today that the U.S. Food and Drug Administration (FDA) has cleared Pluristem's Investigational Drug Application (IND) for a Phase III study of its PLX-PAD cell therapy in the treatment of muscle injury following surgical repair (arthroplasty) of the hip joint due to fracture. Pluristem is in discussions with several EU countries to approve this study in Europe as well and expects to begin patient enrollment in both regions during 2018. Non-dilutive funding totaling [\\$8.7 million](#) (7.4 million Euro) has been granted to this study from Horizon 2020, the European Union's largest research and innovation program.

The Phase III study follows positive [results](#) from a Phase I/II trial which demonstrated significant muscle regeneration when using PLX-PAD cells in total hip arthroplasty patients. The study demonstrated a 300% change in muscle volume ($p=0.004$) and a 500% ($p=0.0067$) change in muscle force at 6 months post-surgery, compared to the control group.

The Phase III, multinational, randomized, double-blind, placebo-controlled study will assess the efficacy and safety of intramuscular (IM) administration of allogeneic PLX-PAD cells for the treatment of muscle injury following arthroplasty for hip fracture, as compared to placebo treatment. Through clinical sites in the U.S. and Europe, 240 patients will be randomized on a 1:1 allocation to be dosed with 150 million PLX-PAD cells or placebo on the day of surgery. The primary endpoint is the change in the short physical performance battery (SPPB) score at week 26 after treatment.

"The FDA's clearance marks the second Phase III study for Pluristem in the U.S. for our PLX-PAD cell therapy and we look forward to begin patient enrollment in 2018," stated Pluristem's President and Co-CEO, Yaky Yanay. "We are encouraged by our prior Phase I/II study results that showed PLX-PAD supported muscle regeneration and we are hopeful that PLX-PAD will be similarly effective for patients in our Phase III study. I am pleased to see the successful execution of our clinical development plan with a series of Phase III multinational studies, which we believe positions Pluristem as one of the most advanced and mature companies in the regenerative medicine industry."

Dr. Tobias Winkler of the Berlin-Brandenburg Center for Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery, the principal investigator of the study, commented, "We look forward to evaluating PLX-PAD's ability to aid muscle regeneration in patients recovering from arthroplasty for hip fracture. Following surgery, many patients do not fully recover and suffer considerable morbidity due to poor muscle regeneration and impaired mobility. If the results of the study show efficacy, then one simple

procedure administering an IM dose of PLX-PAD on the day of surgery may significantly reduce recovery time and recovery costs, while improving quality of life for these patients.”

About Hip Fracture

Femoral neck fracture is the most common form of hip fracture, with mortality rates of up to 36%, and annual treatment costs estimated to be between \$10-\$15 billion in the U.S. alone. Following surgery, many patients do not fully recover due to poor muscle regeneration, leading to significant morbidity, loss of the ability to live independently, and an overall decline in quality of life. The incidence of hip fracture is expected to increase as populations age.

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading developer of placenta-based cell therapy products. The Company has reported robust clinical trial data in multiple indications for its patented PLX cells and is entering late-stage trials in several indications. Our PLX cell products release a range of therapeutic proteins in response to inflammation, ischemia, muscle trauma, hematological disorders, and radiation damage. The cells are grown using the Company's proprietary three-dimensional expansion technology and can be administered to patients off-the-shelf, without tissue matching. Pluristem has a strong intellectual property position; Company-owned and operated, GMP-certified manufacturing and research facilities; strategic relationships with major research institutions; and a seasoned management team.

Safe Harbor Statement

This press release contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, Pluristem is using forward-looking statements when it discusses its Phase III clinical trial of PLX-PAD cells generally as well as its expectation that it will begin patient enrollment in the U.S. and Europe in 2018, its belief that the successful execution of its clinical development plan with a series of Phase III multinational studies positions Pluristem as one of the most advanced and mature companies in the regenerative medicine industry and the possibility that PLX-PAD may significantly reduce recovery time and recovery costs and improve quality of life. 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; Pluristem may encounter delays or obstacles in launching and/or successfully completing its clinical trials; Pluristem's products may not be approved by regulatory agencies, Pluristem's technology may not be validated as it progresses further and its methods may not be accepted by the scientific community; Pluristem may be unable to retain or attract key employees whose knowledge is essential to the development of its products; unforeseen scientific difficulties may develop with Pluristem's process; Pluristem's products may wind up being more expensive than it anticipates; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; Pluristem's patents may not be sufficient; Pluristem's products may harm recipients; changes in legislation may adversely impact Pluristem; 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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