Pluristem Reaches Milestone in its Phase III Muscle Injury Study, Completes 50% Enrollment

Multinational study in the U.S., Israel and Europe targeting to be the first product candidate supporting muscle regeneration after significant trauma such as hip fracture

HAIFA, Israel, December 3, 2019 - Pluristem Therapeutics Inc. **(Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing novel placenta-based cell therapy products, today announced that it has completed enrollment of 50% of the 240 patients planned for its ongoing Phase III PLX-PAD study of muscle regeneration.

There are currently no approved treatments for the post-operative regeneration of injured or weak skeletal muscle, and up to 30% of hip fracture patients die within one year of surgery due to long-term complications resulting from immobility, with high financial costs of hospitalization and rehabilitation.

Pluristem's ongoing Phase III multinational, randomized, double-blind and placebo-controlled study is assessing patients' physical performance scores 26 weeks following surgery after administrating allogeneic PLX-PAD cells for the treatment of muscle injury following arthroplasty for hip fracture, as compared to placebo. Additional efficacy endpoints include muscle strength, muscle mass and volume, hospitalization time and lower extremity measure. Through clinical sites in the U.S., Europe and Israel, 240 patients are being randomized on a 1:1 allocation to be dosed with 150 million PLX-PAD cells or placebo on the day of surgery.

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

Pluristem CEO, Yaky Yanay, stated, "This study marks an important milestone for Pluristem, as we are moving forward with our main global studies and remain on track with recruitment. We believe that our advanced clinical pipeline is geared to bring regenerative medicine into standard-of-care use in hospitals and clinics while providing reduced costs for the healthcare systems. We are grateful to work with dedicated physicians around the world, and with the European Horizon 2020 Program which is funding this study with €7.4 million."

The Principal Investigator of the study, Dr. Tobias Winkler of the Berlin Institute of Health for Regenerative Therapies, Julius Wolff Institute and Center for Musculoskeletal Surgery, commented, "We are eager to evaluate PLX-PAD's ability to aid muscle regeneration in patients recovering from arthroplasty for hip fracture. Many patients do not fully recover after surgery, suffering considerable morbidity due to poor muscle regeneration and impaired mobility. PLX-PAD has the potential to improve and extend quality of life for patients with one simple injection of the cell therapy product."

About Pluristem Therapeutics

Pluristem Therapeutics Inc. is a leading regenerative medicine company developing novel placenta-based cell therapy product candidates. The Company has reported robust clinical trial data in multiple indications for its patented PLX cell product candidates and is currently conducting late stage clinical trials in several indications. PLX cell product candidates are believed to 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; a Company-owned and operated GMP-certified manufacturing and research facility; 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 that its PLX-PAD cells are being targeted to be the first product candidate supporting muscle regeneration after significant trauma such as hip fracture, the potential of its clinical pipeline to bring regenerative medicine into standard-of-care use in hospitals and clinics while providing reduced costs for the healthcare systems and the potential of PLX-PAD to improve and extend the quality of life for patients. 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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