



Pluristem Completes Enrollment of Its Multinational Phase III Study of Muscle Regeneration Following Hip Fracture Surgery

Having recruited patients in the U.S., Europe and Israel, the Company anticipates topline results in the third calendar quarter of 2022

The Company will host a Key Opinion Leader online event on muscle regeneration following hip fracture surgery on November 22 at 9:15am EST

HAIFA, Israel, November 15, 2021 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI) (the "Company"), a leading biotechnology company announced today that its multinational Phase III multicenter, randomized, double-blind, placebo-controlled study, designed to determine the efficacy, safety, and tolerability of intramuscular administration of allogeneic PLX-PAD cells for the treatment of muscle injury following arthroplasty for hip fracture, is fully enrolled with 240 patients. The multinational clinical study includes patients from the U.S., Europe, and Israel, and topline results are expected in the third calendar quarter of 2022.

The Company will host a Key Opinion Leader online event on muscle regeneration following hip fracture surgery on November 22 at 9:15am EST, for registration: <https://Veidan.activetrail.biz/pluristem>

"Reaching our enrollment target for the Phase III PLX-PAD study is an important milestone," said Pluristem CEO and President, Yaky Yanay. "Rising healthcare costs and aging demographic changes present an opportunity for allogenic, placenta-cell derived products to satisfy unmet clinical needs in the area of muscle regeneration following hip arthroplasty. The potential improvement of physical function following this common procedure could redefine the current standard of care and improve patients' lives."

Pluristem's unique technology, based on a state-of-the-art cell expansion system designed to mimic conditions in the human body, provides a 3-D microenvironment where cells are multiplied and developed into therapeutic candidates. PLX-PAD cells secrete proteins to induce tissue healing in response to muscle trauma and inflammation and are applied via intramuscular administration.

During a completed Phase I/II double-blind placebo controlled trial, PLX-PAD cells [demonstrated](#) statistically significant superiority, in the ability to increase muscle strength and volume for patients who have undergone total hip replacement surgery due to osteoarthritis. If approved, PLX-PAD would be a first-of-its-kind innovative treatment for muscle regeneration.

Mr. Yanay concluded, "Hip fracture is a [major cause of hospitalization](#) for seniors and is associated with significant morbidity, mortality, loss of independence, and financial burden.



The annual number of hip fractures worldwide [is expected](#) to surpass 6 million in 2050 due to the increased prevalence of osteoporosis. As healthcare systems search for new opportunities to lower the [cost of care](#) and provide [new treatments](#) for aging populations, our PLX-PAD product candidate could potentially bring novel solutions for soft tissue regeneration.”

Estimated [annual costs of care](#) for patients suffering from hip fractures in the U.S. are between \$10.3 billion and \$15.2 billion. Approximately [20 percent](#) of hip fracture patients die within one year from surgery due to immobility associated diseases, emphasizing the need for better and faster muscle rehabilitation for improved patient outcome. Cell-based therapy for muscle regeneration could have potential for additional applications, including arthroplasty of the shoulders, knees, and other musculoskeletal indications.

About Pluristem

Pluristem is pushing the boundaries of science and engineering to reimagine pharmacological treatments and improve the standard of care. The Company’s cell therapies advance the field of regenerative medicine, with potentially groundbreaking applications for treating damaged muscle, hematology deficiencies, and inflammation. Pluristem sources its therapeutic cells from the placenta, an ethically accepted and potent source. Cells are easy to collect and do not require blood or tissue matching. Cells from one placenta can treat more than 20,000 patients. The Company’s manufacturing platform is a patented and validated state-of-the-art 3D cell expansion system, designed to mimic the human body. Pluristem’s method is uniquely accurate, cost-effective, and consistent batch-to-batch.

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 the expected timing of the Phase III topline results, that the potential use of PLX-PAD cells for patients recovering from hip fractures could redefine the current standard of care and improve patients' lives, that if approved, PLX-PAD would be a first-of-its-kind innovative treatment for muscle regeneration, that the PLX-PAD product candidate could potentially bring novel solutions for soft tissue regeneration and that cell-based therapy for muscle regeneration could have potential for additional applications. 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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