Pluristem Reports Topline Results from its Phase III Study of Muscle Regeneration Following Hip Fracture Surgery

The Company will host an analyst and investor call to discuss the phase III muscle regeneration following hip fracture surgery topline results on July 14 at 9:00 a.m. ET; for registration: https://pluristem.zoom.us/webinar/register/WN_kp_CwQQtR-aFtjAXrdiJpA

HAIFA, Israel, July 13, 2022 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI) ("Pluristem" or the "Company"), a leading biotechnology company, today announced topline results from its multinational double-blind, placebo-controlled phase III study. The Company designed the study 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. The study enrolled 240 patients in the United States, Europe, and Israel.

PLX-PAD was demonstrated to be an effective accelerator of muscle strength and regeneration. A significant increase in Hip Abduction Strength (HAS) was observed at week 26 and week 52 for patients treated with PLX-PAD (n=120), in the injured leg (p=0.047, p=0.0022) and uninjured leg (p=0.073, p=0.0046) compared to placebo (n=120). This new data confirms the results demonstrated in Pluristem's phase I/II study.
The study did not meet the primary endpoint, which was the Short Physical Performance Battery (SPPB) test at week 26. The SPPB is a series of physical performance tests used in older persons to assess lower extremity function and mobility.[1]

PLX-PAD was well tolerated and demonstrated a significant increase in HAS:

- In the injured leg:
    - Patients treated with PLX-PAD cells showed an increase of 3.2kg from reference (week 6) to week 26 compared to 1.3kg in the placebo group, a 2kg difference (p=0.047).
    - Patients treated with PLX-PAD cells showed an increase of 5.01kg from reference (week 6) to week 52 compared to 0.86kg in the placebo group, a 4kg difference (p=0.0022).

- In the uninjured leg:
    - Patients treated with PLX-PAD cells showed an increase of 2.3kg from reference (week 6) to week 26 compared to 0.51kg in the placebo group, a 1.8kg difference (p=0.073).

[1] https://sppbguide.com/

- Patients treated with PLX-PAD cells showed an increase of 3.3kg from reference (week 6) to week 52 compared to a decrease of 0.7kg in the placebo group, a 4kg difference, (p=0.0046).

- When comparing the absolute HAS between study groups (treated versus placebo) at week 52, patients treated with PLX-PAD showed a 2.6kg higher score than placebo treated patients in the injured leg (p=0.0511). A similar benefit was seen in the uninjured leg, with a 2.2kg difference (p=0.113).

The increase in HAS was further supported by a positive trend in a 6-minute walk test at week 52, showing an increase in walking distance:

- PLX-PAD treated patients (N=36) were able to walk 296 meters versus only 266 meters in placebo treated patients (N=45). The 6-minute walk test evaluates the global and integrated responses of all the systems involved in walking (pulmonary, cardiovascular, systemic and peripheral circulation, musculoskeletal function, neuromuscular units, and muscle metabolism), and is an acceptable functional endpoint.

Professor Tobias Winkler from the Center for Musculoskeletal Surgery, Charité Berlin, and the principal investigator of the study, stated: "I am very encouraged by these results. They confirm our phase I/II study results, now presented in an even older patient population with significantly more comorbidities, and I believe that this confirms that regenerative medicine is indeed effective in elderly people. We observed a significant increase in muscle strength, which we believe demonstrates PLX-PAD's ability to trigger muscle regeneration and maintain it over time. As an orthopedic surgeon, I see this increase in muscle strength as meaningful clinical evidence that PLX-PAD can be potentially beneficial for sport-, surgery-, and traumatic muscle-related injuries."

"We were pleased to learn that the data from this phase III study reinforced the data from the phase I/II study, with PLX-PAD demonstrating an increase in muscle strength," said **Pluristem Chief Executive Officer and President, Yaky Yanay**. "While we were disappointed that this significant benefit did not translate to an SPPB score improvement, Pluristem will seek further regulatory advice to find a way to bridge the gap between the clear impact on muscle strength and the functionality score. We believe that we have an important responsibility to make this treatment available for patients, and we will explore business opportunities and partnerships to advance the development of this product candidate."

About Pluristem

Pluristem is pushing the boundaries of science and engineering to produce cell-based products for various industries on a global scale. Pluristem currently operates in the regenerative medicine and food tech sectors and aims to establish partnerships that leverage the company's cell-based technology platform. Pluristem's placental cell-based therapies show potentially groundbreaking applications for treating damaged muscle, hematology deficiencies, and inflammation. The

Company recently launched a landmark collaboration to produce cultured food products with sustainability as a guiding principle.

About the Study and PLX-PAD

This Phase III study is a global, multicenter, randomized, double-blind, placebo-controlled study, designed to evaluate the efficacy, safety, and tolerability of intramuscular administration of allogeneic PLX-PAD cells in patients undergoing hip arthroplasty following fracture. 240 patients were enrolled in clinical study sites in the United States, Europe, and Israel.

The completed Phase I/II double-blind placebo controlled study demonstrated a statistically significant improvement in muscle strength and volume in patients treated with PLX-PAD who underwent total hip replacement surgery due to osteoarthritis.

PLX-PAD cells exhibit regenerative potential due to their capacity to release factors in response to distress signals from tissues that have been damaged by muscle trauma, ischemia, or inflammation. These factors harness the body's repair mechanisms to support tissue regeneration and differentiation. PLX-PAD cells also exhibit immune-modulating capabilities, playing a central role in the body's response to tissue injury.

In addition to muscle recovery following surgery for hip fracture, PLX-PAD is currently being studied in an investigator-initiated Phase I/II study conducted by Tel Aviv Sourasky Medical Center (Ichilov Hospital) for the treatment of steroid-refractory chronic graft versus host disease (cGvHD).

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 belief that the study results demonstrate PLX-PAD's ability to trigger muscle regeneration and maintain it over time, that the increase in muscle strength demonstrated in the study is meaningful clinical evidence that PLX-PAD can be potentially beneficial for a variety of injuries, the belief that the study results confirm that regenerative medicine is indeed effective in elderly people, that Pluristem will seek further regulatory advice to find a way to bridge the gap between the study results showing a clear impact on muscle strength and the functionality score, its belief that it has an important responsibility to make PLX-PAD available for patients, and that it intends to explore business opportunities and partnerships to advance the development of its product candidate. 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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