Pluristem Reports Topline Results from its Phase II Studies of Acute Respiratory Distress Syndrome Associated with COVID-19

HAIFA, Israel, Dec 27, 2021 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI) (the "Company"), a leading biotechnology company, today announced topline results from its Phase II dose escalation studies evaluating the safety and efficacy of intramuscular injections of PLX-PAD cells for the treatment of Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19. The analysis is based on 89 patients enrolled in two Phase II studies in the U.S. (the "U.S. study") and in Europe and Israel (collectively, the "EU study" and together with the U.S. study, the "Studies").

The primary efficacy endpoint was the number of ventilator free days (VFD) from day 1 through day 28 of the Studies. VFD at day 60 and all-cause mortality at days 28 and 60 were part of the secondary efficacy endpoints in the Studies. The Studies did not meet the primary efficacy endpoint of statistically significant improvement of VFD at 28 days. Taking into consideration the baseline risk factors of the ARDS patients, no differences in the safety profile were observed between PLX-PAD and placebo.

In July 2021, Pluristem announced its decision to bring the Studies to early clinical readout based on 89 patients enrolled, instead of the originally planned 180 patients (140 in the U.S. study and 40 in the EU study). The decision came in response to COVID-19's evolution as a disease, and the significant changes in the standard of care, leading to an increase in the severity of conditions of the intubated patients. These changes in the evolution of COVID-19 raised a major concern about the potential variability in the patient population in the Studies. The early termination of recruitment led to a significant reduction in the statistical power of the Studies.

Efficacy trends from the Studies included:

- A single administration of 300 million PLX-PAD cells demonstrated overall better results, compared to other treatment groups
- Patients in the U.S. study treated with a single dose of 300 million PLX-PAD cells (n=14) showed an increased survival rate by 40% at day 60 compared to placebo group (n=14) (50% vs. 35%)
- Patients in the EU Study treated with a single dose of 300 million PLX-PAD cells (n=11) showed an increased survival rate by 27% at day 60 compared to control group (n=12) (64% vs. 50%)
- In the EU Study, patients treated with a single dose of 300 million PLX-PAD cells showed increased VFD at day 28 by 3.6 days, from 0.2 days in the control group (n=12) to 3.8 days in the treated group (n=11)

- In the EU Study, patients treated with a single dose of 300 million PLX-PAD cells showed increased VFD at day 60 by 112% or 6.6 days, from 5.9 days in the control group (n=12) to 12.5 days in the treated group (n=11)

Pluristem's CEO and President, Yaky Yanay said: "Pluristem joined the global effort to fight the evolving and unexpected COVID-19 pandemic. We chose to focus on the most severe intubated patients suffering from ARDS associated with COVID-19, that have no viable treatment to date and are challenging healthcare systems worldwide. With the new coming wave of the Omicron variant, we intend to explore the opportunities based on the efficacy trends obtained from the Studies. I would like to thank everyone who has been involved in the Studies including the patients and their families, our investigators and study personnel, and the team at Pluristem for making extraordinary efforts to conduct these important studies during very challenging times."

About the Studies:

The U.S. Study included 66 patients enrolled to a randomized, double-blind, placebo-controlled, multicenter, parallel-group study, with three treatment groups of PLX-PAD cells - single administration of 300 million cells, single administration of 600 million cells, or 300 million cells administered twice in a one-week interval; and two placebo control groups single administration, and two administrations in a one-week interval. All groups received a study treatment in addition to the best standard medical care according to local practices.

The EU Study enrolled 23 patients in Germany, Bulgaria, and Israel to a randomized, controlled, multicenter, parallel-group study with a single treatment group (single dose of 300 million PLX-PAD cells) in addition to best standard medical care according to local practices, and a control group received the best standard medical care according to local practices.

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 potentially 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 intention to explore opportunities based on the data obtained from the Studies. 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.

Contact:

Dana Rubin,
Director of Investor Relations
+972-74-7107194
danar@pluristem.com