



Pluristem Brings ARDS Associated with COVID-19 Phase II Studies to Clinical Readout

- **The company will analyze data based on patients enrolled to date in COVID-19 Phase II studies in U.S., Europe and Israel**
- **Topline results are expected during the fourth quarter of 2021**

HAIFA, Israel, July 8, 2021 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI) (the "Company"), a leading biotechnology company announced today that it is bringing its Acute Respiratory Distress Syndrome (ARDS) associated with COVID-19 Phase II studies to clinical readout. The Company's COVID-19 program included over 100 patients across two Phase II studies in the U.S., Europe and Israel, and in compassionate use and expanded access programs in the U.S. and Israel. The analysis will be based on 89 patients enrolled in the previously announced two Phase II studies, which investigated the safety and efficacy of Pluristem's PLX cells as a treatment for severe COVID-19 cases complicated by ARDS.

This decision comes in response to COVID-19's evolution as a disease, as well as changes in the standard of care and a decline in the most severe cases. For the same reason, the Company will not pursue plans [announced in December 2020](#) to expand Pluristem's COVID-19 program to Mexico in collaboration with Innovare R&D. Pluristem expects to announce the topline results of the readout during the fourth quarter of 2021.

As part of the clinical readout, Pluristem will examine the safety and efficacy of PLX cells for treating ARDS, a condition associated with a number of illnesses in addition to COVID-19 [including sepsis, smoke and toxic chemical inhalation, head and chest injuries, and pancreatitis](#). ARDS continues to pose a significant clinical challenge that affects [over 200,000 Americans annually, roughly 10 percent of Intensive Care Unit patients and 23 percent](#) of ventilated patients worldwide.

Pluristem continues to advance its product candidate pipeline – PLX-PAD and PLX-R18 – on a number of fronts. Pluristem's PLX-PAD treatment exhibits the potential to stimulate tissue regeneration in response to muscle trauma and inflammation. PLX-PAD is currently in a [Phase III multinational clinical trial](#) testing the safety and efficacy of accelerating muscle regeneration following HIP fracture surgery. Additionally, Pluristem recently reported [positive Phase I topline results](#) from its evaluation of PLX-R18 cells to address incomplete hematopoietic recovery following Hematopoietic Cell Transplantation (HCT). The Company's unique proprietary process and advanced development and manufacturing capabilities enable it to produce PLX cells at significant scale.

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 20,000 patients. The Company's manufacturing platform, the bioreactor, 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 II study clinical readout, the expected examination of the clinical readout in relating to treating ARDS for illnesses and causes in addition to COVID-19, the potential of its product candidates and its pipeline. 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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