Pluristem Expands its Phase II COVID-19 European Clinical Trial to Israel

HAIFA, Israel, October 7, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today that it has received approval from the Israeli Ministry of Health to commence patient enrollment in Israel for the Company's COVID-19 Phase II clinical trial, under the protocol that was approved by the Paul Ehrlich Institute (PEI), Germany's regulatory agency. A total of 40 patients hospitalized with severe COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS) will be enrolled at clinical sites in Israel and Germany.

The Phase II COVID-19 European clinical trial that is being expanded to Israel is in addition to Pluristem's other COVID-19 clinical programs, including a Phase II study and an Expanded Access Program in the U.S., both under the U.S. Food and Drug Administration's (FDA) approved protocol, and a per-patient compassionate use program in Israel.

The primary efficacy endpoint of the Phase II European study titled, "A Randomized, Controlled, Multicenter, Parallel-Group Phase II Study to Evaluate the Efficacy and Safety of Intramuscular Injections of PLX-PAD for the Treatment of severe COVID-19" is the number of ventilator free days during the 28 days from day 1 through to day 28 of the study. Safety and survival follow-up will be conducted up to week 52.

"We believe that the approval from the Israeli Ministry of Health will enable us to advance the treatment of severe COVID-19 patients. As the pandemic continues in Israel, we see it as our mission to treat those severe patients in need. With our broad COVID-19 clinical programs in Europe and the U.S., we are committed to advancing our research and developing a treatment that may help save lives," stated Pluristem CEO and President Yaky Yanay.

PLX Cells for COVID-19

PLX cells are available off-the-shelf and once commercialized, can be manufactured in large scale quantities, which we believe offers a key advantage in addressing a global pandemic. PLX cells are allogeneic mesenchymal-like cells that have immunomodulatory properties that induce the immune system's natural regulatory T cells and M2 macrophages, and thus may potentially reverse the dangerous overactivation of the immune system. Accordingly, PLX cells may potentially reduce the severity of COVID-19 pneumonia, leading hopefully to a better prognosis for the patients. Previous pre-clinical findings of PLX cells revealed therapeutic benefit in animal studies of pulmonary hypertension, lung fibrosis, acute kidney injury and gastrointestinal injury which are potential complications of the severe COVID-19 infection. Clinical data using PLX cells demonstrated the strong immunomodulatory potency of PLX cells in patients post major surgery. Initial clinical data on COVID-19 ICU patients, treated under a Compassionate Use Program, at the conclusion of a 28 day follow up were previously

published. Taken together, PLX cells' potential capabilities with the safety profile observed from clinical trials involving hundreds of patients worldwide potentially position them as a therapy for mitigating the tissue-damaging effects of COVID-19.

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 its proposed study in Israel, its belief that the approval from the Israeli Ministry of Health will enable it to advance the treatment of severe COVID-19 patients, its belief that the ability to manufacture PLX cells in large scale quantities offers a key advantage in addressing a global pandemic, the potential of PLX cells in preventing or reversing the dangerous overactivation of the immune system, that PLX cells may potentially reduce the fatal symptoms of COVID-19 induced pneumonia, and PLX cells' position as a therapy for mitigating the tissue-damaging effects of COVID-19.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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