Pluristem Expands its COVID-19 Program to Europe, Receives PEI Clearance to Commence Phase II Study in Germany

HAIFA, Israel, August 10, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today that Germany's health regulatory agency, the Paul Ehrlich Institute (PEI), has cleared the Company's Phase II clinical protocol for its 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." Forty (40) patients hospitalized with severe cases of COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS) will be enrolled in the study.
The primary efficacy endpoint of the study is the number of ventilator free days during the 28 days from day 1 through day 28 of the study. Safety and survival follow-up will be conducted at day 60, week 26 and week 52.

"We are pleased to expand our COVID-19 program to an additional territory and look forward to commencing a clinical trial of our PLX cells for the treatment of severe COVID-19 cases complicated by ARDS in Europe. Based on our discussions with the PEI, this will be a standalone study, with the active arm compared to the current standard of care. Pluristem is conducting several advanced clinical development programs in Europe which are supported by the Horizon 2020 and, upon receipt of funds, by the European Investment Bank (EIB). We are grateful for their important support of our therapeutic platform. Pluristem is committed to utilizing what we believe is the major competitive advantages of our technological platform and to bringing regenerative medicine to patients in Europe and around the world," stated Pluristem CEO and President Yaky Yanay.

In addition to this study in Germany, Pluristem is currently conducting a Phase II COVID-19 trial in the U.S. which will enroll 140 patients.

PLX Cells for COVID-19

PLX cells are available off-the-shelf and once commercialized, can be manufactured in large scale quantities. Pluristem believes its PLX cells will offer a key advantage in addressing the COVID-19 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 prevent or reverse the dangerous overactivation of the immune system. Accordingly, PLX cells may potentially reduce the incidence and/or 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 at the conclusion of a 28 day follow up from COVID-19 ICU patients that were treated under a Compassionate Use Program, 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 Europe, its belief that its study will be a standalone study, with the active arm compared to the current standard of care, the potential receipt of funds from the EIB, that it is committed to utilizing what it believes is the major competitive advantages of its technological platform and to bringing regenerative medicine to patients in Europe and around the world, when it discusses 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.

Contact:
Dana Rubin
Director of Investor Relations
972-74-7107194
danar@pluristem.com