



U.S. FDA Clears Pluristem's IND Application for Phase II COVID-19 Study

- **140 patients with severe COVID-19 and ARDS to be treated**
- **Primary endpoint: ventilator free days during the main 28-day study period, secondary endpoint includes survival rate and ICU free days**

HAIFA, Israel, May 8, 2020 - [Pluristem Therapeutics Inc. \(Nasdaq:PSTI\) \(TASE:PSTI\)](#), a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for a Phase II study of its PLX cells in the treatment of severe COVID-19 cases complicated by Acute Respiratory Distress Syndrome (ARDS). The study, titled "A Randomized, Double-Blind, Placebo-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" will treat 140 adult patients that are intubated and mechanically ventilated and are suffering from respiratory failure and ARDS due to COVID-19. 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.

The objective of the study is to evaluate the efficacy and safety of one or two intramuscular (IM) injections, in three different dosages, of PLX-PAD for the treatment of ARDS resulting from COVID-19. The primary endpoint determination will be performed at the end of the 28 day main study period. Safety and survival follow-up will be conducted at week 8, 26 and 52. Pluristem has been treating patients suffering from severe complications caused by COVID-19, such as ARDS and inflammatory complications, in the U.S. and Israel through compassionate use programs. Preliminary data from these compassionate use programs in Israel was [reported on April 7, 2020](#). A Clinical Trial Authorization (CTA) has also been filed in Europe for a Phase II COVID-19 trial, with the first European clinical sites planned in Germany and Italy.

"We are very pleased to gain clearance to commence our Phase II COVID-19 study in the U.S. We are shifting gears now with a main focus on a rapid initiation of the clinical trial, leveraging our technological and logistical competitive advantages developed through our clinical trial experience in the U.S. and Europe. We believe we can complete enrollment quickly and we expect to provide guidelines on the expected study duration a few weeks following the commencement of the study," stated Pluristem CEO and President, Yaky Yanay. "In the last few weeks, we have received dozens of applications from physicians and families seeking to participate in the Expanded Access per patient program. We look forward to working with hospitals and physicians on a larger scale to deliver our PLX cells, through an off-the-shelf, easy to use PLX cell product candidate, which may potentially accelerate recovery time from life threatening conditions, and to improve survival, in the most severe COVID-19 cases."

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 and pneumonitis 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. 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 the scope, endpoints, and enrollment of patients in the Phase II COVID-19 study, the rapid initiation of the study, its expectation that it will complete a quick enrollment of its study, that it will be able to provide guidelines on the expected study duration in the coming weeks, that its PLX cell product candidate may potentially accelerate recovery time from life threatening conditions and improve survival in the most severe COVID-19 cases, 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 pneumonitis, 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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