# Pluristem Announces Activation of Clinical Sites and Commencement of Patient Enrollment in U.S. FDA Phase II COVID-19 ARDS Trial

**HAIFA, Israel, June 11, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today the activation of clinical sites and initiation of enrollment in its Phase II U.S. Food and Drug Administration (FDA) study of PLX cells for the treatment of severe COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS). The Company is focused on expanding to clinical sites throughout the U.S. in accordance with the changing dynamic spread of the COVID-19 pandemic, using its advanced operational capabilities and cold chain agility. The trial is expected to include up to 25 sites.

The randomized, double-blind, placebo-controlled, multicenter, parallel-group 140 patient study is evaluating the efficacy and safety of intramuscular (IM) injections of PLX-PAD for the treatment of severe COVID-19 cases complicated by ARDS. The primary endpoint is the number of ventilator free days during the main 28-day study period. Safety and survival follow-up will be conducted at week 8, 26 and 52. Secondary efficacy endpoints include all-cause mortality, duration of mechanical ventilation, ICU free-days, and hospitalization free-days.

"Pluristem is closely following the spread of the COVID-19 pandemic globally as well as the 'hot spots' in the U.S. We are targeting locations that show the highest rate of new cases and incorporating the ready-to-use advantages of our PLX-PAD product candidate. Pluristem's confirmed operational and unique cold chain logistical capabilities enable us to treat patients within hours of notice. We also believe this will enable us to deliver COVID-19 treatments in a timely manner and in the right place, while assisting the healthcare systems in the fight against COVID-19, its complications, and its burden on the medical infrastructure."

**PLX Cells for COVID-19**

PLX cells are available off-the-shelf and once commercialized, can be manufactured in large scale quantities, offering 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 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 its focus on expanding clinical sites throughout the U.S., the expected number of clinical sites it expects will be included in the trial, the belief that its confirmed operational and unique 'cold chain' logistical capabilities enable it to treat patients within hours of notice, its belief that it will be able to deliver potential COVID-19 treatments in a timely manner, and in the right place, while assisting the healthcare systems in the fight against COVID-19, its complications, and its burden on the medical infrastructure and 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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