



## **Israeli Ministry of Health Clears a Path to Allow Per Patient Compassionate Use Treatment of Covid-19 Patients with Pluristem's PLX Cells**

**HAIFA, Israel, March 17, 2020 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing a platform of novel biological products, today announced that the Israeli Ministry of Health has approved Pluristem's request to seek approvals to treat COVID-19 coronavirus patients under the per-patient compassionate use framework in Israel. The Israeli Ministry of Health may approve proposed treatments on a per-patient basis for the use of PLX cell therapy including intra-muscular (IM) administration of PLX-PAD for the proposed treatment of severe pneumonia resulting from COVID-19 and preventing the deterioration of patients towards Acute Respiratory Distress Syndrome (ARDS) and sepsis. Pluristem has not yet submitted any such request for treatment of a specific COVID-19 patient, and there is no assurance that any such request will be approved by Israeli Ministry of Health.

Pluristem recently announced a collaborative agreement with the BIH Center for Regenerative Therapy (BCRT) and the Berlin Center for Advanced Therapies (BeCAT) at Charité University of Medicine Berlin to evaluate the therapeutic effects of PLX cell product candidates for the potential treatment of the respiratory and inflammatory complications associated with the COVID-19 coronavirus.

"Pluristem is highly committed to use its technology, knowledge and expertise in order to attempt to provide a better outcome to patients infected by complications associated with COVID-19. We hope and believe that the ease of use of our PLX cell product candidates, and their being readily available, may play an important role in case there is a need to treat large numbers of patients with respiratory complications. Our collaborative research with Charité of Berlin on our PLX COVID-19 program enables us to accelerate the implementation of our cell therapies candidates towards this indication, as we continue our efforts to expand the program to additional countries," stated Pluristem President and CEO Yaky Yanay.

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 the potential use of its PLX cell product candidates for the proposed treatment of severe pneumonia resulting from COVID-19 and preventing the deterioration of patients towards ARDS, sepsis and death, its commitment to use its technology, knowledge and expertise in order to attempt to provide a better outcome to patients afflicted by complications associated with COVID-19, its hope and belief that the ease of use of its PLX cell product candidates and their being readily available, may play an important role in case there is a need to treat large numbers of patients with respiratory complications, that its collaborative research with Charité of Berlin on the PLX COVID-19 program enables Pluristem to accelerate the implementation of its cell therapies candidates towards this indication, its intention to continue efforts to expand its PLX COVID-19 program to additional countries, the belief that PLX cells being available off-the-shelf and can be manufactured in large scale quantities, may offer a potential key advantage in addressing a global pandemic and the belief that PLX cells may potentially reduce the incidence and/or severity of COVID-19 induced pneumonia and pneumonitis. 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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