Pluristem Expands its Compassionate Use Program: Treated First COVID-19 Patient in U.S. Under FDA Single Patient Expanded Access Program

- **Cleared by FDA to proceed with the treatment in U.S. under Coronavirus Treatment Acceleration Program (CTAP)**
- **Pluristem's main focus: multinational clinical trial of PLX cells for treatment of complications associated with COVID-19**

HAIFA, Israel, April 13, 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 treated its first patient suffering from COVID-19 complications in the United States under the U.S. Food and Drug Administration's (FDA) Single Patient Expanded Access Program, also called a compassionate use program, which is part of the U.S. Coronavirus Treatment Acceleration Program (CTAP), an emergency program for possible therapies that uses every available method to move new treatments to patients as quickly as possible.

The patient was treated with PLX cell therapy at Holy Name Medical Center in New Jersey, an acute care facility that is currently an active site for Pluristem's Phase III critical limb ischemia (CLI) study. Prior to treatment with PLX, the patient was critically ill with respiratory failure due to acute respiratory distress syndrome (ARDS) and was under mechanical ventilation in an intensive care unit (ICU) for three weeks.

"We are receiving many inquiries and requests for treatment from healthcare providers and families worldwide. In parallel with our planned clinical trial, we expect to continue treating patients under compassionate use through the appropriate regulatory clearances in the United States and Israel, as well as expanding treatment under compassionate use in other countries. Our main focus remains however, the initiation of a multinational clinical study," stated Pluristem CEO and President Yaky Yanay.

Pluristem's main target is to initiate a multinational clinical trial as soon as possible for PLX cells in the treatment of patients suffering from complications associated with COVID-19. As the Company focus is the initiation of such clinical trial, it does not intend to provide further updates on the status of patients treated under compassionate use. Pluristem will update on the status and progress of its planned COVID-19 clinical trial program.

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 expectation that it will continue treating patients under compassionate use through the appropriate regulatory clearances in the United States and Israel, that it expects to expand treatment under compassionate use in other countries, that Pluristem's main target is to initiate a multinational clinical trial as soon as possible for PLX cells in the treatment of patients suffering from complications associated with COVID-19, its intention not to provide further updates on the status of COVID-19 patients treated under compassionate use, when it discusses updating on the status and progress of its contemplated clinical trial program, 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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