Pluristem Launches FDA-Cleared COVID-19 Expanded Access Program, Enabling Patient Treatment Outside of Clinical Trial

HAIFA, Israel, August 27, 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 Expanded Access Program (EAP) for the use of its PLX-PAD cells to treat Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19 outside of the Company's ongoing Phase II COVID-19 study in the U.S. The program provides a pathway for patients that are not eligible for inclusion in the Phase II clinical trial to be treated with PLX-PAD cells. The EAP will include up to 100 patients, with the resulting data collected and evaluated alongside Pluristem's clinical trial.

"We are excited to offer expanded access to our PLX-PAD cell therapy for patients in need who are suffering from severe complications of COVID-19," stated Pluristem CEO and President, Yaky Yanay. "The FDA clearance of our EAP follows our recent experience treating COVID-19 patients under compassionate use programs in the U.S. and Israel, and, we believe emphasizes the urgent medical need for new therapeutic options to treat COVID-19 patients who are critically ill. We believe that now is the time for governments and states to ensure medical centers throughout the United States can offer these crucial treatments on a large scale. We, at Pluristem, are committed to harnessing our commercial-scale manufacturing capabilities to deliver on these requirements and make our novel PLX cells with favorable safety profiles available to all in need."

Alongside the EAP in the U.S., Pluristem will continue to advance its two ongoing COVID-19 Phase II clinical trials of its PLX-PAD product candidate for the treatment of severe ARDS in the U.S. and Europe, and treat patients under the compassionate use program in Israel.

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 that it will include up to 100 patients in the EAP and that the resulting data will be collected and evaluated alongside its clinical trial, its belief that the approval of its EAP by the FDA emphasizes the urgent medical need for new therapeutic options to treat COVID-19 patients who are critically ill, the belief that now is the time for governments and states to ensure medical centers throughout the United States can offer crucial treatments on a large scale, its commitment to harnessing its commercial-scale manufacturing capabilities to deliver on these requirements and make its novel PLX cells with favorable safety profiles available to all in need, 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 incidence and/or severity of COVID-19 pneumonia and pneumonitis leading hopefully to a better prognosis for the patients, 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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