



## **Pluristem Treated First Three COVID-19 Patients in Israel under Compassionate Use**

- **Expects to treat more patients in Israel in the coming days**
- **Company is in discussions with regulators in the U.S and Europe to define its clinical strategy for COVID-19**

**HAIFA, Israel, March 30, 2020 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing a platform of novel biological therapeutic products, announced today that since its [last update on COVID-19](#), it has dosed three patients in two different hospitals in Israel under a compassionate use program for the treatment of COVID-19, as approved by the Israeli Ministry of Health. Pluristem expects to enroll additional patients in Israel in the coming days and anticipates providing updates on clinical outcomes once significant data has been gathered.

All three treated patients are in a high-risk group based on age and preexisting conditions, have been experiencing severe respiratory failure, and intubation with a ventilator. Pluristem is closely following the medical condition of these patients in conjunction with the hospitals' medical professionals delivering the care.

Pluristem is prepared for immediate ramp-up of PLX cell production with consistent batch-to-batch cell production quality through its GMP certified manufacturing facilities in order to meet potential demand.

"In this time of emergency, we are honored to be taking part in the global effort to support patients and healthcare systems. We watch with great admiration the endless efforts of the outstanding medical teams at the hospitals, and we would like to thank them for their collaboration and support. It is our hope that our mutual desire to help patients will result in improved outcomes for those hard hit by the life threatening complications of COVID-19," stated Pluristem CEO and President, Yaky Yanay. "In addition to our current activity in Israel, we are in discussions with regulators in the U.S and Europe to define our clinical strategy for COVID-19. Pluristem's advanced manufacturing capabilities enable us to serve potential need of treating large numbers of patients under compassionate use and clinical studies across numerous countries and hospitals in accordance with our expansion program and regulatory approvals. We are facing a very different global condition right now, and the entire Pluristem team is committed to being an important part of the solution."

## **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.

The potential therapeutic effects of PLX cells for the treatment of respiratory and inflammatory complications associated with the COVID-19 are currently being studied through a collaborative agreement between Pluristem and the BIH Center for Regenerative Therapy (BCRT) and the Berlin Center for Advanced Therapies (BeCAT) at Charité' University of Medicine Berlin.

## **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 to enroll additional patients in Israel in the coming days and anticipation of providing updates on clinical outcomes once significant data has been gathered, or when it discusses preparation for immediate ramp-up of PLX cell production with consistent batch-to-batch cell production quality through its manufacturing facilities in order to meet potential demand, or when it discusses that its advanced manufacturing capabilities enable it to serve potential need of treating large numbers of patients under compassionate use and clinical studies across numerous countries and hospitals in accordance with its expansion program and regulatory approvals, when it discusses the benefits and potential therapeutic effects of PLX cells that they may prevent or

reverse the dangerous overactivation of the immune system, that they may potentially reduce the incidence and/or severity of COVID-19 pneumonia and pneumonitis leading hopefully to a better prognosis for the patients or that PLX cells' potential capabilities with the safety profile observed from clinical trials potentially position them 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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