



Pluristem Provides 28-Day Follow Up for Ventilator-Dependent COVID-19 Patients under Compassionate Use Program in Israel and U.S.

Update is provided in advance of the company's recruitment of first patient for its phase II Covid-19 study

- **87.5% survival rate of patients on invasive mechanical ventilation injected with PLX cells**
- **75% of patients no longer in need of any mechanical ventilation**
- **62.5% of the patients discharged alive from the hospital**
- **A 28-day study period is also the primary endpoint timeline for Pluristem's recently announced FDA Phase II study**

HAIFA, Israel, May 14, 2020 - Pluristem Therapeutics Inc. (Nasdaq:PSTI) (TASE:PSTI), a leading regenerative medicine company developing a platform of novel biological therapeutic products, today reported an update on the status of COVID-19 infected patients treated with PLX cells under a compassionate use program in Israel and the FDA Single Patient Expanded Access Program in the U.S. All treated patients were in Intensive Care Units (ICU), on invasive mechanical ventilation and suffered from Acute Respiratory Distress Syndrome (ARDS) at the time of treatment. As of today, a total of 18 patients were treated in Israel and in the U.S., of which 8 (1 in the U.S. and 7 in Israel) so far have completed a 28-day follow up period.

28-day follow up highlights for 8 patients treated with PLX cells:

- The survival rate of the 8 patients treated with PLX cells was 87.5%
- 75% were off any mechanical ventilation
- 62.5% were discharged alive from the hospital compared to 3.3% (38 out of 1151 patients) in data published in the NY area during March-April 2020 for patients requiring mechanical ventilation and discharged alive¹

Notwithstanding the Company's prior intention not to provide further updates on the status of patients treated under compassionate use, the Company is now providing this update in response to a substantial increase in shareholder inquiries, following the FDA clearance of Phase II study

¹ Richardson S et al. *Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area*. JAMA 2020. doi:10.1001/jama.2020.6775

and prior to recruitment of the first patient. The Company intends to provide a final update regarding the compassionate use program in Israel and the FDA Single Patient Expanded Access Program in the U.S. once it has completed such programs and after it has completed its previously announced Phase II study with respect to the use of its PLX cells for the treatment of severe COVID-19 cases complicated by ARDS.

“We are highly encouraged by this data. The 28-day follow up time marker is important, as our Phase II study’s primary efficacy endpoint is the number of ventilator free days during the 28-day study period from day 1 through day 28,” stated Pluristem CEO and President, Yaky Yanay. “We are currently focused on initiating the Phase II clinical study in the U.S., where we expect to treat the first patient in the coming days. Simultaneously, we continue to help treat patients through our compassionate use and FDA Single Patient Expanded Access Programs in Israel and the U.S.”

PLX Cells for COVID-19

PLX cells are available off-the-shelf and once commercialized, can be manufactured in large scale quantities. Pluristem believes its PLX cells will offer a key advantage in addressing the COVID-19 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 intention to provide updates on the remaining patients treated under the compassionate use program in Israel and an Expanded Access Program in the U.S. once such programs, and its Phase II study, conclude, its intention to continue to treat patients in its compassionate use and Expanded Access Programs, the timing of the enrollment of its first patient in its Phase II study in the U.S., 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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