



## **Pluristem Provides Update on COVID-19: Preparedness, Current Phase III Clinical Trials Status and Treatment Development Activity**

**HAIFA, Israel, March 26, 2020 - [Pluristem Therapeutics Inc.](#) (Nasdaq:PSTI) (TASE:PSTI)**, a leading regenerative medicine company developing a platform of novel biological products, today issued an update to its shareholders from its Chief Executive Officer and President, Yaky Yanay.

Dear Fellow Shareholders,

In light of the novel coronavirus pandemic (COVID-19), today we wanted to provide an update on the impact of the coronavirus pandemic on our business and on our ongoing Phase III clinical studies of PLX-PAD in the treatment of Critical Limb Ischemia (CLI), and muscle regeneration following hip fracture, as well as update you on our actions to provide a PLX cell product as a potential treatment for the respiratory and inflammatory complications associated with COVID-19.

In managing our ongoing global clinical trials, as well as our daily operations at our headquarters in Israel, we are taking all necessary precautions for the safety and well-being of patients, healthcare providers involved in our trials, and our employees.

Pluristem continues its operational and manufacturing activities, subject to the directives of the Israeli Ministry of Health, with a dedicated team on site. In addition, Pluristem is using remote work technologies that enable other activities to be conducted without the need for a physical presence in our facilities. Today, and into the foreseeable future, we believe that we are well positioned to operate through the COVID-19 pandemic. Our allogenic, off-the-shelf approach and our advanced manufacturing capabilities enabled us to complete the manufacturing of the entire stock needed to complete all of our current clinical studies. We currently hold supplies of PLX cells in inventory in Israel, and in secure storage facilities in Europe and the U.S.

With regard to our operational business, while we are preparing for the potential ramp up in production to supply PLX-PAD cells for the potential treatment of COVID-19 complications, we have rapidly implemented a significant cost reduction plan. Our goal is to make sure that we will be able to operate through any unforeseen or foreseen scenario, and I am glad to say that the company's stakeholders, including employees and suppliers, are fully cooperating with our

request and have agreed to our significant cost reduction plan. Until we have better clarity on the global impact of COVID-19, we have applied a cost saving plan relating to employee compensation which includes a 50% reduction in compensation for C-level executives and our management team, and a gradual reduction of between 20% to 50% for all employees according to managerial level, with non-management employees having the lowest reduction. I would like to say that the past few days have shown me once again how committed the Pluristem team is to the success of our company. I feel proud and blessed to lead such a talented and committed team and I would like to thank each and every one of them for their loyalty and dedication.

### **Clinical Trials**

While we continue to enroll and treat patients in our two ongoing pivotal Phase III studies of our PLX-PAD product candidate for the treatment of CLI and muscle regeneration following hip fracture, we do so within the new guidelines provided by the U.S. Food and Drug Administration's (FDA), "[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)", issued on March 18, 2020, and the European Medicines Agency's (EMA) "[Guidance on the Management of Clinical Trials during the COVID-19 \(Coronavirus\) pandemic](#)" issued on March 20, 2020. In Israel, our clinical studies are subject to the directives of the Israeli Ministry of Health.

As of today, we have enrolled over 80% of the patients in our pivotal Phase III CLI trial, and close to 60% in our Phase III study of muscle regeneration following hip fracture. While we continue enrollment in both studies, from what we have seen in the last few weeks, we believe it is reasonable to expect a certain slowdown in the enrollment rate, as it is our commitment and obligation to ensure the safety and health of our patients and medical team.

We are currently evaluating the impact of COVID-19 on the original timelines for our interim analysis and full study readouts and will continue to provide updates on our progress in our future quarterly reports.

In the last few months, we have been holding discussions with the FDA and EMA in order to confirm and agree on the changes in the parameters and final protocol design of the interim analysis of the CLI clinical data, which may lead to conditional marketing approval in Europe. I expect to be able to update you on those understandings in the coming weeks.

### **A Message for Patients**

For patients participating in our studies, patient safety remains our top priority. We are working closely with the clinical trial sites and evaluating options and adjustments. In the next few days, we expect the clinical trial sites will publish guidelines for continuing to conduct these studies during this pandemic. I wish you all good health.

### **Treatment of Complications from COVID-19**

Pluristem is fully committed to the global drive towards developing and delivering healthcare products to potentially treat severe pneumonia resulting from COVID-19. Towards this end, we

are collaborating with the BIH Center for Regenerative Therapy (BCRT) and the Berlin Center for Advanced Therapies (BeCAT) at Charité University of Medicine to evaluate the therapeutic effects of our PLX cell product candidates for the treatment of the respiratory and inflammatory complications associated with COVID-19. We also received the Israeli Ministry of Health's clearance to seek approvals to treat COVID-19 patients under a per-patient compassionate use framework in Israel. Currently, our main effort is to initiate treatment of patients as soon as possible. We are now holding discussions with regulators to define our clinical strategy for COVID-19, while we start with compassionate use programs in order to provide the product immediately to patients. We are targeting a potential full development plan in the U.S., Europe and Israel with the goal of supporting global healthcare systems' tremendous effort to fight off COVID-19 and bring life back to normal.

Pluristem is a strong company, and I believe we are well prepared for the challenges and opportunities we face with the COVID-19 situation. Pluristem is committing and harnessing all of its knowledge, experience and dedication to be part of the global solution for this pandemic. Our team is passionate about improving the wellbeing of patients and we believe that our regenerative medicine product candidate is ideally suited to today's healthcare challenges. I thank you all for your support and loyalty to Pluristem and I wish you and your families good health.

Sincerely,  
Yaky Yanay  
Chief Executive Officer and President

### **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 belief that it is well positioned to operate through the COVID-19 pandemic, with ample supplies of PLX cells in inventory in

Israel, and in secure storage facilities in Europe and the U.S., that it is preparing for the potential ramp up in production to supply PLX-PAD cells for the potential treatment of COVID-19 complications, its belief that it is reasonable to expect a slowdown in the enrollment rate of its clinical studies, its expectation to provide updates with respect to its original timelines for its interim analysis and full study readouts in its future quarterly reports as well as its discussions with the FDA and EMA regarding changes in the parameters and final protocol design of the interim analysis of the CLI clinical data which may lead to conditional marketing approval in Europe, that it is targeting a potential full development plan in the U.S. and Europe with the goal of supporting global healthcare systems' tremendous effort to fight off COVID-19 and its belief that its regenerative medicine product candidate is ideally suited to today's healthcare challenges. . 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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