



## Pluristem CEO Issues Shareholder Update

HAIFA, Israel, September 15, 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,

This year, we saw the unprecedented need for the collaboration between industry and government in order to meet the challenge of the COVID-19 pandemic. Pluristem is fully engaged in this effort and is harnessing all of its knowledge, experience, and dedication to improve the wellbeing of patients. We believe our regenerative medicine product candidates are ideally suited to today's healthcare challenges. Through our late stage pipeline of product candidates and indications, we are paving the way towards marketing and commercialization, and strengthening our global presence through strategic collaborations including our most recent one with the Abu Dhabi Stem Cells Center.

[As reported](#) on July 21, 2020, we are heading into a pivotal year with four clinical readouts expected including: interim analysis of the Phase III study in Critical Limb Ischemia (CLI), top line efficacy results of the Phase III study in muscle regeneration following hip fracture, top line efficacy results of the Phase II study in COVID-19 and data analysis of the Phase I study in incomplete hematopoietic recovery following hematopoietic cell transplantation (HCT).

### **Phase III CLI Study and Interim Data Analysis**

In the fourth quarter of calendar 2020, we expect to announce the interim analysis results for our global pivotal Phase III study of PLX-PAD in CLI. We continue to enroll patients in the full clinical study in the U.S., Europe, and Israel and we recently added clinical sites as part of our efforts to introduce our PLX cells at additional key medical centers. The interim and/or final data set results are expected to enable discussions with both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regarding the filing of a Biologics License Application (BLA).

### **Phase II COVID-19 Study**

Over the past few weeks, we have shifted our clinical site openings from the New York area to other regions in the U.S., as we follow the spread of the COVID-19 pandemic, and we are also

considering adding clinical partners to accelerate site openings. In line with these steps, we are updating our expectation of completing enrollment in the first quarter of calendar year 2021. In the U.S., under the Expanded Access Program, up to 100 patients suffering from severe COVID-19 complicated by Acute Respiratory Distress Syndrome (ARDS), who are not eligible for inclusion to the Phase II study, may be treated with PLX-PAD and the gathered data will be evaluated alongside the Phase II study data. In Europe, we continue to advance the Phase II clinical study which has been cleared in Germany to commence patient enrollment, and in Israel we continue to treat patients under the per-patient Compassionate Use program.

### **Financial Update**

Pluristem had \$59 million in cash, cash equivalents and bank deposits as of June 30, 2020.

Moving forward into our 2021 fiscal year, which coincides with our Jewish New Year, we reiterate Pluristem's commitment to all of our stakeholders including shareholders, patients, employees and our partners. While this year brought unprecedented challenges, we witnessed, more than ever, Pluristem's resilience and ability to face those challenges. This is a credit to our dedicated and passionate employees who have a profound commitment to excellence. We are proud of our tenured team of 160 employees, over 45% of which have been with the Company for 5-10 years. I truly believe that our very strong culture is the one reason that Pluristem has won recognition for being one of the best places to work in Israel, for four years in a row. More importantly, we see the commitment of our employees as one of the main factors driving our success and we are all committed to continuing to drive for such success in the coming year.

Sincerely,  
Yaky Yanay  
Chief Executive Officer

### **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 its regenerative medicine product candidates are ideally suited to today's healthcare challenges, its belief that it is heading into a pivotal year with four clinical readouts expected including interim analysis of the Phase III study in CLI, top line efficacy results of the Phase III study in muscle regeneration following hip fracture, top line efficacy results of the Phase II study in COVID-19 and data analysis of the Phase I study in incomplete hematopoietic recovery following HCT, that it expects the interim and/or final data set results from the Phase III CLI study to enable discussions with both the FDA and the EMA regarding the filing of a BLA, that it expects to complete enrollment of its Phase II COVID-19 study in the first quarter of calendar year 2021 and its belief that its strong culture is the one reason that it has won recognition for being one of the best places to work in Israel, for four years in a row. 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.

**Contact:**

Dana Rubin  
Director of Investor Relations  
972-74-7107194  
danar@pluristem.com